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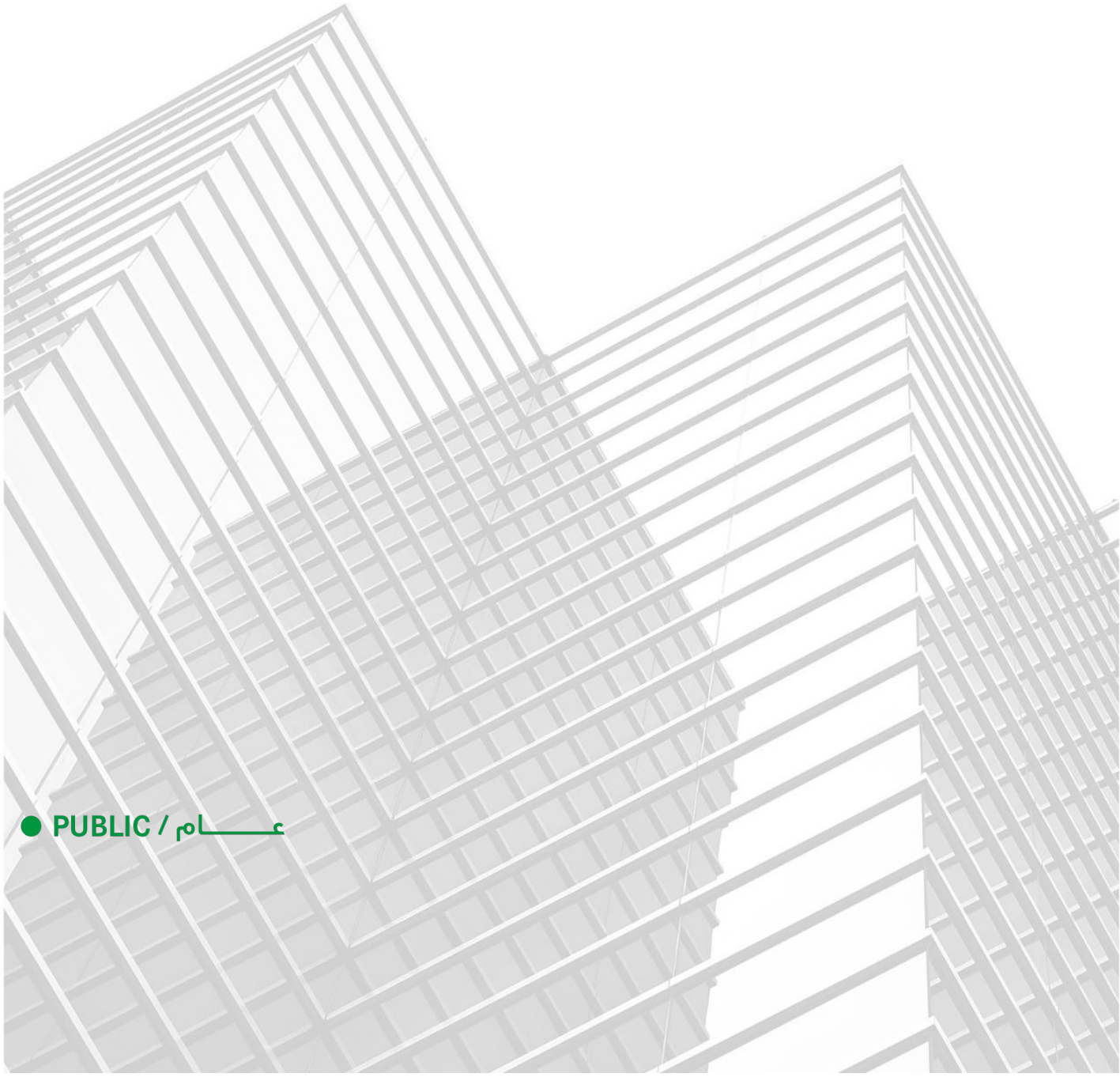
DEPARTMENT OF HEALTH

Bioconvergence Policy



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1.Policy Purpose and Brief

1.1 Bioconvergence is an emerging multidisciplinary field that integrates the life sciences—including biology, technology and Omics—with cutting-edge disciplines such as artificial intelligence, engineering, nanotechnology, and computational sciences. This fusion is redefining the landscape of next-generation healthcare, enabling innovative and holistic solutions [1,2]. Recognizing Bioconvergence transformative potential, the Department of Health Abu Dhabi (DoH) as the regulatory authority for the healthcare sector in Abu Dhabi is proactively embracing and cultivating Bioconvergence principles to build a future-ready, innovation-led, and knowledge-driven health and life sciences ecosystem.

1.2 Bioconvergence as a multifaceted approach to innovation with applications that are continuously evolving. Key areas of Bioconvergence application include digital healthcare, precision medicine, synthetic biology, and biomanufacturing. This field also encompasses advanced therapies like bioprinting of organs and nanorobotics as well as reproductive engineering and biocomputing. Other applications involve technologies such as DNA-based data storage, Biomachine interfaces, and the development of on-demand medicine production for managing or eradicating diseases.

1.3 The establishment of clear, comprehensive policy for bioconvergence is much needed for a resilient and agile health life sciences ecosystem aspiring to a pioneering position and competitiveness for the Emirate of Abu Dhabi. Without harmonized definitions and regulatory oversight for these rapidly evolving applications could lead to legal ambiguity, uneven standards, and an erosion of public trust. Key consequences include the potential for widened healthcare inequality, significant cybersecurity vulnerabilities from bio-digital integration, and ethical dilemmas surrounding reproductive engineering and human enhancement. Furthermore, a clear policy will enhance responsible innovation as regulatory uncertainty increases the potential for malicious misuse of technologies or unforeseen ecological disruptions from engineered organisms.

1.4 The Department of Health Abu Dhabi is issuing this policy document to provide the foundation and the direction to establish a clear regulatory direction, governance and enabling framework for Bioconvergence development in Abu Dhabi with the following goals:

1.4.1 Align Abu Dhabi's Health Life Sciences Ecosystem Strategic direction with international futuristic innovation trends; emphasizing the importance of Bioconvergence as a key scientific research and innovation approach to enhance healthcare access, drive efficiency and excellence in healthcare solutions facilitating the Emirate commitment to be at the forefront of global health innovation.

1.4.2 To ensure a cohesive, adaptive, and forward-looking regulatory environment that facilitates responsible innovation, mitigates emerging risks, and maximizes the societal and economic value of bioconvergent solutions throughout their development journey while ensuring that risks and unintended consequences are avoided or minimized.

1.4.3 To ensure that Bioconvergence innovation outcomes to be technically and clinically sound additionally are ethically grounded, socially acceptable, and accessible.

1.4.4 Ensuring an enabling environment where collaboration and integration of Bioconvergence stakeholders are promoted to harness Bioconvergence

potential and overcome the traditional barriers that hinder breakthrough innovation.

1.4.5 Enable community engagement to communicate priorities, educate and promote participation in enhancing and facilitating Bioconvergence Innovation to ensure effective implementation of innovation

1.4.6 Support Bioconvergence innovators from concept to Health Life Sciences Ecosystem impact.

1.5 The policy outlines the main concepts that need to be nurtured and enhanced for a full embracement of Bioconvergence. By fostering collaboration across academia, startups, and industry; encouraging early stakeholder engagement; and promoting responsible innovation and regulatory foresight, a strong and well-regulated Bioconvergence ecosystem can catalyze investment, create high-value jobs, and contribute to the growth of Abu Dhabi's knowledge-based economy.

1.6 Through tailored and risk based regulatory framework customized to each phase within the Bioconvergence innovation cycle, DoH will work with its partners institutions to provide platforms and channels to stimulate the formation of startups, strengthen industry partnerships, and promote international collaboration, thereby reinforcing Abu Dhabi's leadership in the global health innovation landscape. Moreover, DoH will introduce regulatory sandbox environments with tailor-made measures and robust monitoring mechanisms dictated by the context and the maturity of the innovation phase to enable cutting edge research and innovation drive the development of future-ready, evidence-based solutions.

1.7 All Annexes attached to this policy form an integral part of this Policy and are considered equivalent in its legal status.

1.7.1 Annex 1: Risk Based approach towards most important Bioconvergence Applications in Health Life Sciences.

1.7.2 Annex 2: Stage wise regulatory approach -Bioconvergence Innovation Life Cycle.

1.8 This policy should be considered in parallel to the following

1.8.1 Other DoH policies such as but not limited to:

1.8.1.1 Policy for Trusted Research Environment (TRE)

1.8.1.2 Precision Medicine Policy

1.8.1.3 Policy on Biobanking

1.8.1.4 DoH Policy on Genomics

1.8.1.5 DoH Digital Health Policy

1.8.1.6 Policy on Use of Artificial Intelligence (AI)

1.8.1.7 Policy Governing Human Biomedical Research

1.8.2 Other DoH standards (Refer to DoH website for the most updated standards, policies and guidelines)

18.3 UAE Federal and local Laws and regulations in relevance to the subjects covered by the Bioconvergence policy (data laws, professional practice laws, pharmacy laws, organ transplant laws, …….)

18.4 International agreements.

2.Definitions and Abbreviations		
No.	**Term / Abbreviation**	**Definition**
2.1	AI	Artificial intelligence.
2.2	ATMPs	Advanced Therapy Medicinal Products.
2.3	DoH	Department of Health Abu Dhabi
2.4	DURC	Dual-Use Research of Concern.
2.5	EMA	European Medicines Agency
2.6	FDA	Food and Drug Administration.
2.7	GCP	Good Clinical Practices.
2.8	GDPR	General Data Protection Regulation
2.9	GMP	Good Manufacturing Practices.
2.10	HIPAA	Health Insurance Portability and Accountability Act
2.11	HLF	Health Life Science
2.12	ISO 27001	Information security management systems
2.13	QMS	Implement a comprehensive Quality Management System.
2.14	R&D	Research and Development.
2.15	RTOs	Research and Technology Organizations.
2.16	RWE	Real-World Evidence.
2.17	TTOs	Technology Transfer Offices.
2.18	VoD	The Valley of Death.
2.19	WHO	World Health Organization.

Term / Definition		
2.20	Adaptive Risk Assessment	Dynamic risk approach evolving with scientific and technological changes.
2.21	Biocomputing	Using cells and cellular components for computation
2.22	Dual-Use Research (DUR)	Research with legitimate intent can also be misapplied for harmful purposes.
2.23	Dual-Use Research of Concern (DURC)	Research that poses significant risk to public health, agriculture, national security, or the environment if misused.
2.24	First-in-Human (FIH)	First-in-human trials are a key step in Bioconvergence Based Solution development, where the solution is already tested in vitro, in animals or in other preclinical studies is administered to a Human for the first time.
2.25	GxP	GxP is a general abbreviation for the "good practice" quality guidelines and regulations. The "x" stands for the various fields, including the pharmaceutical, Bio Research, Manufacturing, Laboratory, Clinical, Documentation etc.
2.26	Human Biomedical Research	Scientific research aims to understand and improve human health, disease, and functioning at the molecular, cellular, organ, and whole-body levels. It encompasses a wide range of activities, from basic studies of fundamental biological processes to the development and testing of new treatments and diagnostic tools.
2.27	Internet of Everything (IoE)	Is the evolutionary term for Internet of Things (IOT) where the concept expands beyond devices to include people, processes, and data—emphasizing a fully interconnected ecosystem.
2.28	Internet of Things (IoT)	refers to a vast network of physical devices—ranging from everyday household items to sophisticated industrial machines—that are embedded with sensors, software, and connectivity features. These devices collect and exchange data over the internet, allowing them to monitor, communicate, and interact with their environment or with each other
2.29	Omics	This is a collective term for technologies that allows the comprehensive identification and quantification of the complete set of molecules (eg, proteins, carbohydrates, lipids) of a biological system (cell, tissue, organ, biological fluid, or organism) at a specific point in time.
2.30	Organizational Excellence	Framework ensuring operational integrity and adherence to safety, quality, and ethics.
2.31	Proteomics	This is the comprehensive identification and quantification of the complete set of proteins of a biological system (cell, tissue, organ, biological fluid, or organism) at a specific point in time.

2.32	Real-World Evidence (RWE)	Evidence derived from real-world data like EHRs or patient-reported outcomes.
2.33	Reference Regulatory Authority	A regulatory authority designated as a "reference authority" or "stringent regulatory authority" implying their regulations, guidance documents, decisions and assessments are recognized and relied upon examples but not limited to: • **World Health Organization (WHO):** While not a direct regulatory authority for individual countries, the WHO plays a significant role in setting global standards and guidelines for drug regulation. • **US Food and Drug Administration (FDA):** A prominent regulatory authority for drugs and medical devices in the United States. • **European Medicines Agency (EMA):** The regulatory body for medicinal products in the European Union. • **UK Medicines and Healthcare products Regulatory Agency (MHRA):** The UK's regulatory authority for medicines and medical devices. • **Emirates Drug Establishment (EDE):** The UAE's primary regulatory authority for pharmaceuticals and medical devices.
2.34	Reference Standardization/ harmonization Body	• International Conference for Harmonization (ICH): **ICH achieves harmonization** through developing guidelines and technical requirements for the development, approval and safety monitoring of medicines. • International Medical Device Regulators Forum (IMDRF). It focuses on coordinating regulatory approaches and facilitating convergence in medical device regulations worldwide. • International Organization for Standardization (ISO) contribute through the development of standards used in medical device regulation
2.35	Regulatory Sandbox	Controlled environment allows innovators to test solutions under regulatory supervision.

2.36	Virtual Twin	Virtual twins are digital replicas that go beyond basic 3D modeling: they can predict future behaviors, enabling more precise and personalized patient care. This technology is transforming healthcare by addressing challenges and driving innovation, offering tailored treatments and improving overall outcomes. Virtual twins in healthcare accelerate improvement of medical devices and therapies by enabling manufacturers to simulate and refine products before physical production. In hospitals, virtual twins create digital models of the healthcare facilities, ensuring a safer and more secure environment for patients, staff and visitors.

3. Policy Content

3.1 **Definition of Bioconvergence**[1,2,7]

3.1.1 Bioconvergence represents the integration of life sciences with other scientific and technological fields particularly engineering, computer science, science physics and advanced material to develop innovative solutions in health medicine and beyond. This integration encompasses omics technologies that enable large-scale data analysis of biological molecules. See Figure 1

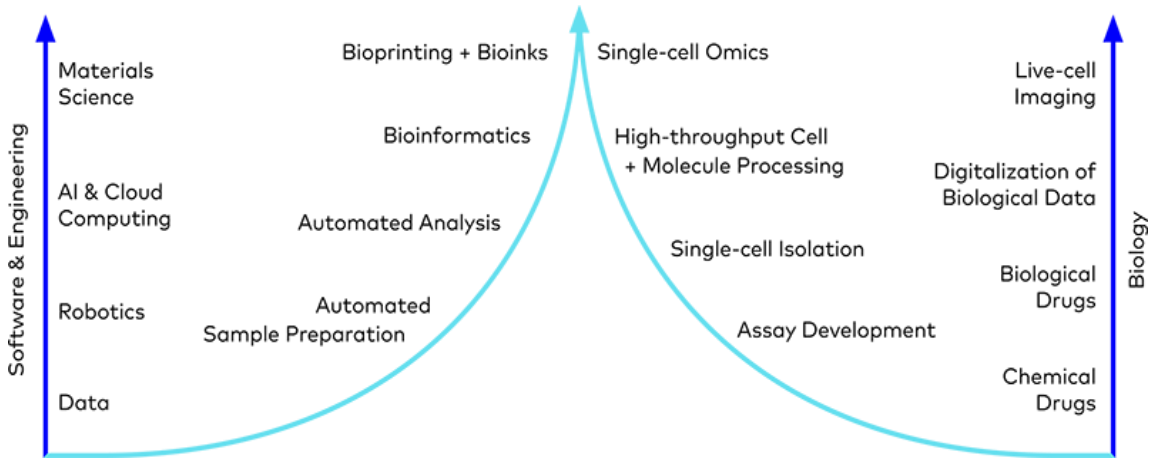


Figure 1: Bioconvergence

3.1.2 This multidisciplinary approach transcends traditional sectoral boundaries between sciences to address complex medical challenges, improve diagnostics, personalize treatments, and leveraging data to enhance health system efficiency. It facilitates a holistic understanding of complex biological systems, leading to advancements in personalized medicine, diagnostics, and therapeutic strategies such as robotics, nanorobotics, nanotechnology, synthetic biology and other applications to drive medical and healthcare advancements. [1,2,7]

3.1.3 Recognizing the transformative potential of this multidisciplinary approach, the Department of Health (DoH), through this policy document, sets the foundation to the establishment of a comprehensive regulatory framework that fosters innovation while upholding safety, efficacy, and ethical integrity. This policy sets out clear guidelines for the governance, evaluation, and advancement of Bioconvergence innovations within Abu Dhabi's healthcare ecosystem.

3.2 Significance of Bioconvergence

3.2.1 The emergence of Bioconvergence marks a paradigm shift in how healthcare innovation is conceived, developed, and deployed. From AI-powered bioengineering platforms and neurotechnology to bio-robotics and smart diagnostics, Bioconvergence innovations have the potential to revolutionize patient care, enhance precision medicine, and drive sustainable health systems.

3.2.2 Bioconvergence as a systematic approach is expected to transform the ability to manipulate living matter and address global challenges in health, food security, and sustainability hence it also presents new form of risks that needs to be acknowledged and addressed at early stages by well-structured policies.

3.2.3 There are many examples of what Bioconvergence could enable scientists, governments, research institutions, and companies:

3.2.3.1 Visualize, measure, identify, and manipulate biological systems at molecular scales.

3.2.3.2 Treat genetic instructions in DNA, RNA, and amino acids like a language that can be written, edited, and executed with high precision to synthesize useful materials or organisms.

3.2.3.3 Collect, digitize, store, and analyze genetic instructions, referred to as genomes, from thousands of individuals, along with their physical, mental, and health traits, to correlate how specific genetic instructions interact with the environment to produce distinct traits.

3.2.3.4 Combine complex biological and nonbiological processes, such as bioelectronic interfaces for sensing or stimulating biological systems, in support of medicine, agriculture, and manufacturing.

3.2.4 Bioconvergence applications are expected to offer[4]

3.2.4.1 Increased control and precision in biology intervention.

3.2.4.2 Enhanced capabilities to engineer and reprogram human and non-human organisms

3.2.4.3 Increased efficiency and productivity of R&D

3.2.4.4 Growing potential for interfaces between biological systems and digital technologies

3.2.5 Innovations and claimed discoveries resulting from Bioconvergence present novel regulatory, ethical, safety, and interoperability challenges. Without a structured and forward-looking policy that embraces flexibility within a clear governance framework, such technologies may be under-regulated, inconsistently evaluated, or inequitably implemented—risking patient safety, environmental security, biosafety, biosecurity and, most importantly, public trust.[3]

3.3 Bioconvergence Policy and regulatory framework strategic goals

A cohesive, inclusive and risk-based policy framework for Bioconvergence is essential to:

3.3.1 Promote and facilitate responsible innovation while safeguarding patients, public health, environment and ethical standards.

3.3.2 Promote cross-sectoral collaboration across academia, industry, regulators, and healthcare providers within Health Life Sciences Eco system in Abu Dhabi- and with other ecosystems locally, regionally and internationally.

3.3.3 Enable dynamic governance that evolves with scientific advancement and societal needs.

3.3.4 Clarify responsibilities and ensure synergy among innovators, regulators, healthcare providers, and patients.

3.3.5 Streamline regulatory pathways providing regulatory predictability and reducing time-to-market without compromising safety, efficacy and access:

3.3.5.1 Define regulatory expectations at each stage of the innovation lifecycle.

3.3.5.2 Ensure safety and efficacy of developed solutions / products.

3.3.6 Ensures ethical integrity, and equity.

3.3.7 By outlining clear principles and processes, this policy aims to support a balanced ecosystem that fosters innovation while upholding the core values of public health, patient safety, and equity.

3.4 Bioconvergence Governance Framework

3.4.1 To fully leverage the significant potential of Bioconvergence in enhancing health and living conditions, while simultaneously addressing potential risks, a comprehensive conceptual framework has been developed (see appendix 1). This framework is structured around the stages of Bioconvergence innovation and serves as the foundation for governance and regulatory oversight, for each element per stage, within the innovation stages. In alignment with this framework, the DoH Bioconvergence policy has adopted a balanced approach, incorporating the following strategies:

3.4.1.1 Risk-based approach to mitigate risks associated with the various applications of Bioconvergence.

3.4.1.2 A strategic, stage-based regulatory framework for guiding the development, evaluation, authorization, and post-market oversight of bioconvergent innovations in healthcare / life sciences.

3.4.1.3 Inclusivity to all stakeholders: This policy is co-developed, endorsed, and to be implemented with shared ownership by all stakeholders, including academic researchers, industry leaders, regulators, payers, and civil society to ensure alignment and accountability across the innovative lifecycle.

3.4.2 Risk Based Approach:

3.4.2.1 Bioconvergence as an approach for surge of innovation in biology carries profound and unique risks and issues[4, 21]. These risks introduce a unique set of considerations which, if not managed properly, could potentially outweigh the promised benefits,

3.4.2.1.1 Biology is self-replicating, is self-sustaining, and does not respect jurisdictional boundaries. For example, new genetically engineered gene drives applied to the vectors can be difficult to control and can potentially do permanent damage to ecosystems.

3.4.2.1.2 The interconnected nature of biology can increase the potential for unintended consequences. Changes to one part of a system can have cascading effects and unintended consequences across entire ecosystems or species.

3.4.2.1.3 Low barriers to entry for dual-use technologies, such as access to commercial CRISPR kits, 3D printing and others, potentially leading to harmful or unintended outcomes, raise significant concerns and need to be addressed.

3.4.2.1.4 Forging consensus among more than one value system is challenging —at the individual, cultural, societal, academic and national levels.

3.4.2.1.5 Unequal access could perpetuate socioeconomic disparity, with potentially regressive effects.

3.4.2.1.6 Data and bio-specimen misuse/dual use without compliance with ethical and data privacy regulations

3.4.2.2 Application specific Risks [23] The integration of diverse scientific disciplines through Bioconvergence is driving a new wave of innovation in healthcare, offering groundbreaking applications that enhance disease prevention, diagnosis, treatment, and patient care. Some of these applications, their definition and their potential risks are listed in annex 1.

3.4.2.3 In here the main application are listed:

3.4.2.3.1 Digital Healthcare and Precision Medicine

3.4.2.3.2 Bioprinting of Organs and Other Individualized Therapies

3.4.2.3.3 Reproductive Engineering

3.4.2.3.4 Biomachine Interfaces including Computer -Human Interfaces

3.4.2.3.5 Biotechnology/ Biomanufacturing Materials and Devices (Engineering Biology)

3.4.2.3.6 Biocomputing and DNA-Based Data Storage

3.4.2.3.7 Manage, cure or eradication of Many Diseases

3.4.2.3.8 On-Demand Medicine Production

3.4.2.3.9 Synthetic Biology

3.4.2.3.10 Xeno-Bioengineering:

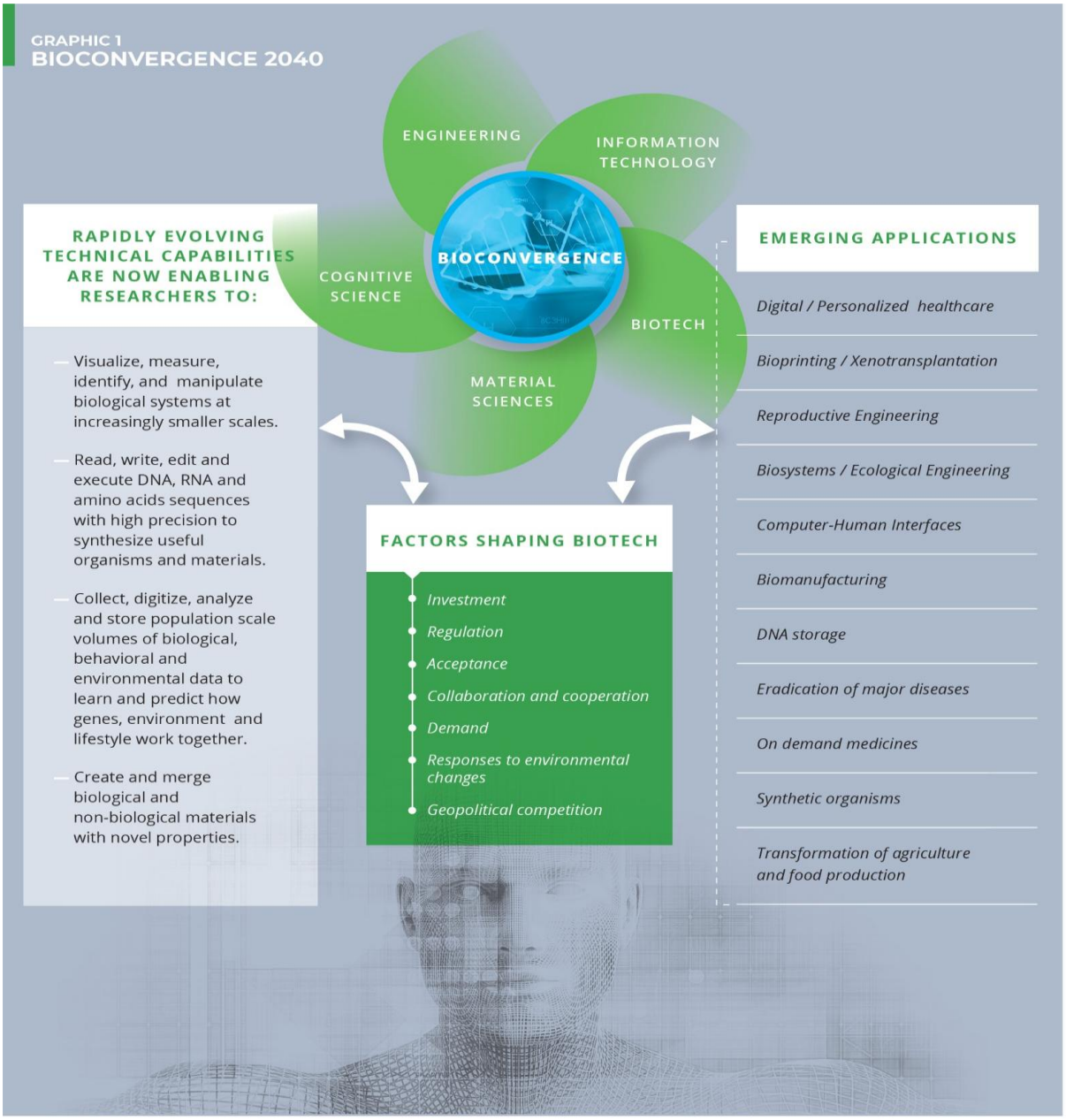


Figure 2: Bioconvergence emerging applications [23]

3.4.3 Policy framework structured around stages of the innovation lifecycle to stimulate purposeful, impactful & Cross Border innovation.

3.4.3.1 DoH believes that Bioconvergence policy needs to embrace a forward-looking approach ensuring stage-appropriate risk containment, coherence and successful transition between stages, enabling sustainability, growth and maximizing the positive short- and long-term impact on health and ecosystem.

3.4.3.2 This policy is structured around a conceptual framework that follows the innovation lifecycle [8], tailored for Abu Dhabi Health Life Sciences Ecosystem. Its purpose is to provide guidance and contain risk from ideation and concept development stage up to widespread adoption and sustained impact of bioconvergent health technologies / solutions or products.

3.4.3.3 The distinct stages of innovation that are considered in this policy document are namely:

3.4.3.3.1 Stage 1: Ideation and concept development followed by a solid proposal: Encouraging creative problem-solving, early-stage exploration, and multidisciplinary collaboration to define promising Bioconvergence opportunities.

3.4.3.3.2 Stage 2: Research and Development (R&D): Supporting the generation of scientific evidence, validation of prototypes, and preclinical testing, with a focus on ethical, safe, and reproducible practices.

3.4.3.3.3 Stage 3: Early Deployment: Providing pathways for pilot clinical trials, real-world testing, and stakeholder feedback to validate safety, efficacy, and operational feasibility.

3.4.3.3.4 Stage 4: Upscaling, Granting Regulatory Approval and Commercialization: Outlining regulatory approval processes and compliance pathways to ensure that innovations are ready for market entry and broader healthcare integration.

3.4.3.3.5 Stage 5: Lifecycle Management, Post-Market Surveillance& Innovation Feedback that includes continuous improvement based on Post marketing mandatory follow up and Outcome-based Success Metrics.

3.4.3.4 A successful innovation cycle that adopts Bioconvergence approach is characterized by early interdisciplinary collaboration, integrated data use, ethical foresight, and continuous feedback between scientific discovery, clinical application, and societal needs. It promotes agile development, iterative testing, and real-world validation, supported by adaptive regulation that evolves in tandem with technological advancement.

3.4.3.5 Each stage is accompanied by targeted regulatory reviews, licensing pathways, and expert guidance to ensure seamless progression from lab to market. By embedding innovation governance within this lifecycle model, the policy ensures that Bioconvergence solutions are developed responsibly, evaluated rigorously, and scaled effectively for public benefit.

3.4.3.6 Through this structured approach, the policy aims to provide innovators and stakeholders with clarity, predictability, and support at each phase—ultimately accelerating the delivery of safe, effective, and equitable bioconvergent solutions to the healthcare system.

3.5 Bioconvergence: Key concepts for Governance, Ethical approach and success

In all the stages the following concepts emerge as key for achieving its goals for DoH as a policy setter and for stakeholders whether other regulatory authorities, industry, academia and financing bodies.

3.5.1 Responsible Research [4,5,6,22] Bioconvergence offers powerful opportunities to develop innovative solutions that are disruptive and bring impactful improvement in health outcomes strengthening healthcare systems worldwide. Misuse of the research resources, whether data, material or biologic components, or the research outcomes, could be referred to as dual-use research and dual-use research of concern.

3.5.1.1 Dual-Use Research: Research conducted for legitimate purposes that generates knowledge, information, products, or technologies that can be utilized for both benevolent and harmful purposes.[5]

3.5.1.2 Dual-Use Research of Concern (DURC): Life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.[6]

3.5.1.3 Awareness: Ensuring that Bioconvergence serves the public good requires shared commitment to sponsible research practices from all stakeholders involved. DoH, guided by the World Health Organization (WHO) as the leading global authority on public health, works to raise awareness of dual-use risks, promote safe and ethical research practices, and support the development of governance mechanisms to ensure this objective if fulfilled. One of the important goals of Bioconvergence policy is to shape a research environment in Abu Dhabi's Health Life Sciences Ecosystem that fosters innovation while safeguarding public trust, safety, and well-being.

3.5.1.4 In this regard, researchers, industry, companies, startups, teams, academia, individuals and any other party involved in Bioconvergence research, development and implementation should consider the following documents to ensure that Bioconvergence across the full cycle of innovation are well guided and comply with responsible research international and local standards:

3.5.1.4.1 DoH Standard on Human Biomedical Research on research on human subjects
3.5.1.4.2 Global guidance framework for the responsible use of the life sciences: mitigating biorisks and governing dual-use research.[6]
3.5.1.4.3 Responsible AI Standard (DoH)
3.5.1.4.4 Abu Dhabi Healthcare Information and Cyber Security Standard (ADHICS)(DoH)

3.5.2 Interdisciplinary, Intersectoral and international Collaboration

3.5.2.1 Bioconvergence as an approach emphasizes the value of seamless collaboration across the entire health and life sciences ecosystem enabling stakeholders—from academia to industry, and from clinicians to investors—to work synergistically from the earliest stages of discovery through to commercialization. This integrated model is increasingly recognized as essential for accelerating the predictability, scalability, and precision of biotech innovation.

3.5.2.2 Bioconvergence fuels collaborations building on an entrepreneurial culture. DoH is committed to fostering a collaborative health life science ecosystem that embraces trust and mutual respect among all stakeholders to ensure Bioconvergence initiatives will achieve the desired outcomes. Such an environment is essential to bring together a wide range of stakeholders—including academic institutions, research organizations, startups, pharmaceutical and medtech companies, investment firms and funds, as well as other government entities.

3.5.2.3 Recognizing that innovation in Bioconvergence thrives on diversity of thought and shared expertise across borders, DoH actively supports both national and international partnerships. Engaging with global platforms and encouraging cross-border collaboration not only accelerates the development of advanced health technologies but also ensures alignment with international standards and ethical practices. In this regard, DoH seeks to position local researchers and companies within a globally connected research and innovation landscape. This approach enhances knowledge

exchange, strengthens capacity, and contributes to the responsible and impactful application of convergence in healthcare that benefits public health and scientific progress.

3.5.2.4 Beyond Academia and traditional Bioconvergence partners such as Medtech and Research based BioPharma, DoH highlights the significance of aligning and engaging in the following sectors:

3.5.2.4.1 The concerned government Agencies and Regulatory Bodies.

3.5.2.4.2 Healthcare Providers and Medical Institutions: Hospitals and clinics offer practical insights into patient needs and facilitate the translation of Bioconvergence innovations into clinical practice.

3.5.2.4.3 Technology Companies: Firms specializing in artificial intelligence, data analytics, and software development contribute essential tools and expertise for managing and interpreting complex biological data.

3.5.2.4.4 Investment and Venture Capital Firms including private equity firms: These entities provide the necessary financial support to drive research, development, and commercialization of Bioconvergence technologies. DoH acknowledges the need to eliminate silos among funding bodies that tend to adopt specific focus areas.

3.5.2.4.5 Technology Transfer Offices and similar purposes not for profit organizations play a crucial role in supporting innovators in healthcare. They help navigate challenges like the "Valley of Death," which refers to the difficult phase where innovations often fail due to lack of funding or support. By providing guidance and preventing avoidable mistakes, TTOs ensure that healthcare innovations progress effectively from concept to implementation.

3.5.2.4.6 Incubators and accelerators: Incubators and accelerators are essential components of the innovative ecosystem, serving as strategic enablers in the advancement of Bioconvergence. Their role extends beyond early-stage support, encompassing the vision of physical infrastructure, access to interdisciplinary expertise, tailored mentorship, regulatory and commercialization guidance, and connections to funding networks and industry stakeholders. Incubators and accelerators facilitate cross-sector collaboration, de-risking early-stage development, and enabling the translation of complex innovations into scalable, market-ready solutions.

3.5.2.5 DoH, as a regulator and policy enabler, plays a pivotal role in setting up opportunities for collaboration and engaging stakeholders in productive dialogue by:

3.5.2.5.1 Actively engaging startups / applicants who submitted compelling concepts and proposals, seeking their alignment and productive engagement with the above-mentioned sectors to ensure success of Bioconvergence projects.

3.5.2.5.2 Support a dynamic HLS ecosystem through partnerships, technical guidance, and forward-looking regulatory frameworks,

3.5.2.5.3 Align innovation with public health priorities.

3.5.3 Regulatory alignment, Quality, Safety & Efficacy

One of the most important roles for DoH is paving the way for Bioconvergence projects to get regulatory approvals locally and internationally. This is by ensuring that startups work on their transformative Bioconvergence solutions starting from the very early stages to generate evidence to ensure that the solutions are safe, ethical, scientifically sound and ready complying with local and international regulatory requirements.

3.5.4 Entrepreneurship

3.5.4.1 Fostering a Culture of Entrepreneurship

3.5.4.1.1 Promoting entrepreneurship is a key enabler of innovation in Bioconvergence. An entrepreneurial mindset enhances the ability to anticipate unmet healthcare needs, identify emerging opportunities, and develop novel solutions that meet evolving market demands. Globally, vibrant life sciences clusters are underpinned by strong entrepreneurial ecosystems, where innovation is translated into real-world impact.

3.5.4.1.2 DoH is committed to work with stakeholders to cultivate an enabling environment for entrepreneurs operating at the intersection of health, technology, and science. This includes facilitating access to knowledge resources, open data, mentorship, and strategic networks across research institutions, academia, finance, and industry.

3.5.4.1.3 As part of this effort, policy measures will emphasize the importance of developing clear proofs of concept, defining effective go-to-market strategies, securing smart investment, attracting skilled talent, and supporting the sustainable growth of startups into regional and global markets. By embedding entrepreneurship into the national Bioconvergence strategy, DoH aims to stimulate the creation and scaling of innovative startups, ultimately strengthening the health innovation ecosystem and contributing to economic growth.

3.5.4.2 The Valley of Death

3.5.4.2.1 The Valley of Death (VoD) reflects a series of challenges facing technology-based companies during their early development stages. The impact of VoD is more visible in the life sciences sector: life sciences entail huge R&D investments while its commercialization takes longer time being highly regulated especially when compared to other industries.[10,11,12]

3.5.4.2.2 Underdeveloped business models at every stage of innovation starting with the proposal's approval are one of the main struggles behind inability to attract funding.

3.5.4.2.3 Scaling production from lab to industry is also a complex and resource-intensive, requiring targeted support for early-stage innovation including funding[3].

3.5.4.2.4 To bridge this gap, it is essential to assemble multidisciplinary teams with strong entrepreneurial and technical competencies, engage experienced advisors to secure diverse funding sources. Without robust business models based on market research and proper needs assessment, Bioconvergence project initiators, whether startups or teams struggle to gain investor confidence and get enough funding needed to validate their concepts and further prove market readiness. This deepens the commercialization gap and jeopardizes the survival of promising innovations. See Figure 2

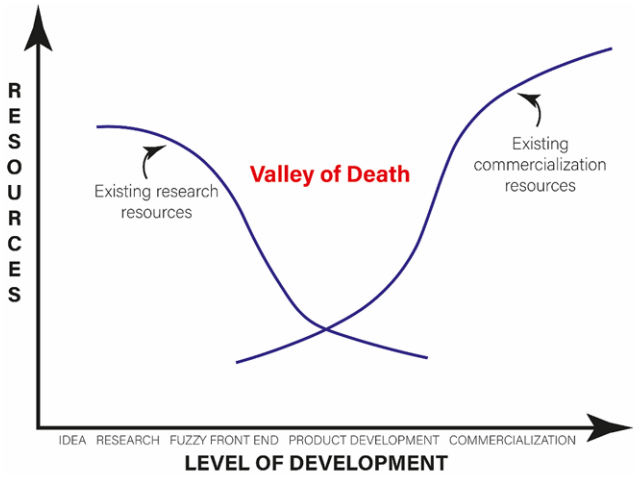


Figure 4: Valley of Death [12]

3.5.5 Organizational Excellence in Bioconvergence

To ensure the highest standards of operational integrity and innovation in Bioconvergence solutions, all applicants pursuing the Bioconvergence project should demonstrate strict compliance with the Organizational Excellence framework. DoH will conduct systematic audits and evaluations to verify adherence to these standards before authorizing deployment. Guided by US FDA Organizational Excellence Pillars for Software / AI as Medical Device regulation[18, 20] we had adapted the organizational Excellence to Bioconvergence area, specifically when a medical product / healthcare solution is targeted.

3.5.5.1 Ensuring patient safety is a fundamental priority in Bioconvergence solutions. Bioconvergence solutions should prioritize patient safety through comprehensive risk management practices, including:

3.5.5.1.1 Conducting thorough risk assessments to identify potential hazards associated with Bioconvergence solutions, encompassing biological, mechanical, and digital risks. These assessments should be periodically reviewed and updated in response to emerging findings, regulatory changes, and technological advancements.

3.5.5.1.2 Developing and implementing a structured risk mitigation plan, incorporating preventive measures, emergency protocols, and continuous safety monitoring. This plan should adhere to international safety frameworks and best practices.

3.5.5.1.3 Ensuring that informed consent is obtained from patients and stakeholders, with clear communication of risks, benefits, and available alternatives. Accurate records of both digital and paper-based consent should be maintained for compliance and auditing purposes.

3.5.5.1.4 Establishing a robust system for the monitoring and reporting of adverse events, in alignment with national and international medical safety standards, to enable prompt corrective actions and ensure legal compliance.

3.5.5.1.5 Complying with relevant safety regulations, such as but not limited to ISO 14971 (Risk Management for Medical Devices), ISO 13485 (international standard for quality management systems (QMS) for medical devices) and relevant guidelines from the FDA, EMA and WHO.

3.5.5.1.6 Where appropriate, engaging in DoH regulatory sandbox programs to evaluate and validate innovative approaches under controlled regulatory conditions.

3.5.5.2 Product Quality [19,20]: maintaining exceptional product quality is crucial for the success and credibility of Bioconvergence solutions. To ensure consistent performance, safety, and regulatory compliance, the following key practices should be implemented:

3.5.5.2.1 Implement a comprehensive to monitor product consistency, safety, and effectiveness, with routine inspections, third-party audits, and process validation, ensuring compliance with the relevant ISO standards.

3.5.5.2.2 Document, define, and continually enhance all processes related to product development, testing, and implementation. Emphasis should be placed on automation, AI integration, and predictive modeling to increase efficiency and minimize errors.

3.5.5.2.3 Ensure rigorous clinical validation, ethical review, and adherence to global regulatory standards, including those mandated by the FDA, EMA, and WHO.

3.5.5.3 Clinical Responsibility [19,20]: to ensure the safe and responsible application of Bioconvergence technologies, it is essential to maintain strict clinical oversight and accountability. The following practices are vital to achieving this goal:

3.5.5.3.1 Ensuring compliance with DoH healthcare regulations, industry best practices, and ethical guidelines across all operational aspects.

3.5.5.3.2 Providing specialized training and support to medical professionals and end-users to facilitate the safe and effective use of Bioconvergence technologies. Training should incorporate AI transparency, risk mitigation strategies, and evidence-based application methodologies.

3.5.5.3.3 Conducting post-market surveillance and complying with DoH adverse event report plan to monitor the clinical impact of Bioconvergence solutions and implement necessary improvements. This process should involve Real-World Evidence (RWE) collection to assess long-term efficacy and safety.

3.5.5.3.4 Establishing protocols for clinical trials and pilot studies before large-scale deployment. These trials must adhere to the Declaration of Helsinki, Good Clinical Practices (GCP), and specific requirements for Advanced Therapy Medicinal Products (ATMPs).

3.5.5.4 Data Governance & Cybersecurity Responsibility: given the integration of digital and biological systems, cybersecurity is a critical component. Bioconvergence solutions shall:

3.5.5.4.1 Implement stringent data protection measures to safeguard patient information and proprietary data, ensuring compliance with UAE standards and regulation such as ADHICS, UAE PDP and ISO 27001.

3.5.5.4.2 Establish proactive technology stack, process and protocols for detecting, preventing, and responding to cybersecurity threats, ensuring compliance with global cybersecurity frameworks (e.g., ISO 27001, NIST Cybersecurity Framework).

3.5.5.4.3 Conduct regular cybersecurity audits and employee training programs to mitigate the risk of data breaches and AI-driven cyber threats.

3.5.5.4.4 Comply with DoH standard and regulations of cybersecurity requirements.

3.5.5.4.5 Comply with all federal and local laws and regulations of UAE (e.g. Federal Law No.2 of 2.19)

3.5.5.5 Proactive Culture: To achieve sustained success and innovation, Bioconvergence solutions should cultivate a proactive organizational culture that prioritizes continuous growth and ethical practices. The following key elements are essential:

3.5.5.5.1 Continuous innovation and improvement through interdisciplinary research, AI-driven insights, and real-world testing.

3.5.5.5.2 Cross-disciplinary collaboration between biology, engineering, AI, and healthcare professionals to drive breakthrough advancements.

3.5.5.5.3 Ethical decision-making and transparency in all aspects of product development, ensuring responsible AI deployment and bioethical integrity.

3.5.5.6 Ethical and Social Responsibility: Bioconvergence solutions shall be developed and deployed with a strong commitment to ethical principles and social responsibility. Addressing societal concerns while fostering innovation ensures public trust and acceptance. Key practices include:

3.5.5.6.1 Ensuring that innovative Bioconvergence solutions are accessible to diverse populations, including underserved and marginalized communities, while preventing technology-induced disparities.

3.5.5.6.2 Following strict ethical guidelines for AI-based decision-making in healthcare, ensuring responsible use of gene-editing, synthetic biology, and regenerative medicine techniques.

3.5.5.6.3 Upholding human rights by ensuring that no Bioconvergence technology infringes upon privacy, bodily autonomy, or social justice principles.

3.5.5.6.4 Promoting widespread awareness and education on Bioconvergence technologies to foster informed public discourse, trust, and acceptance.

3.5.5.7 Risk Analysis & Mitigation: effective risk management is crucial to the successful implementation of Bioconvergence solutions. Risks identification, evaluation, and mitigation should be implemented to ensure that potential hazards are systematically addressed and controlled throughout the development lifecycle.

3.5.5.7.1 A multi-tier risk assessment framework, overseen by the DoH, will be established for Bioconvergence solutions, including risk identification, analysis, evaluation, and mitigation planning. Table 1[21] is an example:

Table 1: Illustrative Framework adopted from AAAS-FBI-UNICI,NASEM, and Tucker Frameworks[12-15]

			Convergent Risk Scenarios		
			In Silico *Design of a Pathogen*	In Silico *Synthesis of a Pathogen*	*Brain-Computer Interface Exploitation*
Risk Assessment	Probability	Adversary	Nation state, nonstate group, or individual	Nation state, nonstate group, or individual	Nation state, nonstate group or individual
		Timeline	Near term (0 to 5 years)	Mid term (6 to 10 years)	Long term (11+ years)
		Democratization	Moderate	High	Very High
		Vulnerabilities	Open access data, open source software	Limited customer verification	Wireless connectivity, cybersecurity
		Needed scientific expertise and skills	Synthetic biology, genomics, bioinformatics	Synthetic biology, bioinformatics	Neuroscience, computer science, electronics
		Governability	Low	Moderate	Moderate
	Consequences	Magnitude of potential consequences to economies, political systems, society, health, environment, and agriculture	Moderate	High	Very High
		Sufficient existing countermeasures	None	None	None
Risk			Moderate	Moderate	Very High

3.5.5.7.2 Risk management plans should align with ISO 14971 (Risk Management for Medical Devices)

3.5.5.7.3 AI-based predictive analytics should be incorporated to identify potential hazards.

3.5.5.7.4 Mitigation strategies should address environmental risks, unintended gene interactions, and biosecurity concerns, ensuring comprehensive safety protocols.

3.5.5.7.5 Adaptive risk assessment methodologies will be developed to accommodate emerging risks, with periodic updates to the risk management framework to reflect new scientific insights and technological advancements.

3.5.5.7.6 Responsible research international standards should guide the risk analysis and mitigation plans.

3.5.5.8 Infrastructure for Bioconvergence Organizational Excellence

Robust and adaptive infrastructure is a foundational pillar for success across all stages of Bioconvergence innovation —from early-stage research to clinical deployment and market readiness as it is essential for conducting high-quality research, prototyping, and clinical validation in accordance with international standards. DoH emphasizes the importance of both internal and external

infrastructure that collectively supports scientific excellence, operational efficiency, and regulatory compliance. Whether developed internally or accessed through strategic partnerships, infrastructure must support the scientific, technological, regulatory, and operational demands of these multidisciplinary initiatives.

3.5.5.8.1 Physical and Technical Infrastructure: Investment in state-of-the-art physical facilities is essential to enable cutting-edge research, prototyping, and clinical testing. This includes:

3.5.5.8.1.1 Advanced laboratories equipped for multidisciplinary work (e.g., synthetic biology, nanotechnology, AI-integrated diagnostics).
3.5.5.8.1.2 Bioengineering platforms, clean rooms, and GMP/GCP-compliant environments.
3.5.5.8.1.3 Specialized instrumentation, such as high-resolution imaging systems, gene sequencers, or robotic automation tools.
3.5.5.8.1.4 Such infrastructure must align with the specific technical requirements of each Bioconvergence innovation, ensuring safety, reliability, and scalability.
3.5.5.8.1.5 compliance monitoring and reporting

3.5.5.8.2 Digital and Data Infrastructure: A secure and scalable digital Infrastructure is equally critical. It should support:

3.5.5.8.2.1 High-capacity data collection, integration, and real-time analytics

3.5.5.8.2.2 Secure storage systems with compliance with data protection laws (e.g., encrypted servers, secure cloud services).

3.5.5.8.2.3 Interoperability and data-sharing mechanisms to facilitate collaboration across institutions and sectors.

3.5.5.8.2.4 Strong digital infrastructure also underpins the ethical and efficient use of AI and data-driven approaches, which are core to many Bioconvergence solutions.

3.5.5.8.3 Internal Operational Systems: In line with the principles of Organizational Excellence explained earlier, institutions must establish efficient internal processes and governance mechanisms to support:

3.5.5.8.3.1 Project management and quality assurance.

3.5.5.8.3.2 Risk assessment and mitigation strategies.

3.5.5.8.3.3 Regulatory tracking and reporting.

3.5.5.8.3.4 Resource allocation and performance monitoring.

3.5.5.8.3.5 These systems ensure smooth execution of complex innovation projects, especially within multi-partner or cross-sectoral teams.

3.5.5.8.4 Strategic Collaborations and External infrastructure: Bioconvergence often relies on accessing specialized capabilities beyond a single organization's internal setup. Engagement with:

3.5.5.8.4.1 Academic institutions.

3.5.5.8.4.2 Research centers.

3.5.5.8.4.3 Industry partners.

3.5.5.8.4.4 Incubators and accelerators.

3.5.5.8.4.5 Participation in international consortia and innovation ecosystems also expands access to shared research infrastructure, open science initiatives, and globally harmonized methodologies.

3.6 Licensing Requirements:

3.6.1 In alignment with DoH's commitment to promoting responsible innovation and safeguarding public health, all activities conducted under Bioconvergence innovation projects must adhere to established licensing frameworks. Licensing ensures that all participating entities, individuals, and facilities meet the required standards of safety, quality, and ethical compliance throughout the innovation lifecycle.

3.6.1.1 **Facility Licensing**: All facilities engaged in research and development must hold valid licenses from the concerned authorities authorizing the specific activities conducted within them.

3.6.1.1.1 For Abu Dhabi based facilities, these facilities need to seek Abu Dhabi concerned authorities to get the required licenses. If Abu Dhabi facilities are involved in Human Biomedical Research non-clinical or clinical studies, then additional licensing is required from DoH.

3.6.1.1.2 Additionally, these facilities should demonstrate their compliance with applicable biosafety and biosecurity requirements, standards and regulations, particularly when handling biological materials, hazardous substances, or live models.

3.6.1.2 **Researcher Licensing**: Individuals conducting human biomedical nonclinical or clinical research must be appropriately licensed or credentialed DoH, in accordance with national regulations governing human subject protection, ethics, and clinical research standards.

3.6.1.3 **Startup Licensing**: Startups participating in Bioconvergence initiatives must be formally registered and licensed by the relevant licensing authorities in Abu Dhabi and qualified / credentialed by DoH, with consideration given to their organizational readiness, governance structure, and the maturity level of the proposed innovation.

3.6.1.4 **Consortia Licensing**: Entities forming a consortium must each hold valid licenses from the authorities concerned in their countries of origin and / or Abu Dhabi, relevant to their scope of contribution. In addition, the consortium must be governed by a formal legal agreement or contract that clearly outlines the roles, responsibilities, resource commitments, and governance structure of each participating entity. This agreement must be duly signed and authenticated by all parties to ensure transparency, accountability, and legal enforceability. All participating institutions are expected to operate within their licensed capacities to uphold regulatory compliance throughout the project lifecycle.

3.6.2 Maintaining a high standard of organizational excellence is a key requirement [20] for all entities involved in the development of Bioconvergence innovations, whether startups, academic spin-offs, or multi-institutional consortia. Organizational excellence as explained in section (7.5) reflects the entity's capacity to manage complex innovative projects, comply with regulatory and ethical standards, and ensure the safety, quality, and integrity of the developed solutions.

3.6.3 Startups and consortia are expected to maintain these standards as a prerequisite for obtaining and retaining licenses issued by DoH. Periodic assessments may be conducted to evaluate organizational performance and ensure ongoing alignment with the policy objectives.

3.6.4 DoH will issue licensing requirements in response to emerging technologies and evolving national or international regulatory standards

3.7 Other enablers of success

3.7.1 International Outreach: to build a competitive global Bioconvergence ecosystem, the following mechanisms may be implemented:

3.7.1.1 Partnerships:

3.7.1.1.1 Establishing strong collaborations between universities, research institutions, healthcare providers, and private sector companies to accelerate the research and development of Bioconvergence solutions.

3.7.1.1.2 Engaging in joint initiatives with international regulatory agencies, innovation hubs, and leading industry players to facilitate knowledge exchange and ensure Bioconvergence solutions meet global requirements.

3.7.1.2 Consultations with stakeholders:

3.7.1.2.1 Conducting ongoing engagement with key stakeholders, including policymakers, scientific experts, and industry representatives, to ensure that Bioconvergence regulations evolve in line with technological advancements.

3.7.1.2.2 Organizing public consultations to incorporate feedback from healthcare professionals, patients, and investors, creating a regulatory framework that balances innovation with safety and accessibility.

3.7.1.3 Funding:

3.7.1.3.1 DoH along with its partners will work on establishing government-led funding programs, including grants, to support Bioconvergence research and accelerate the commercialization of innovative healthcare solutions.

3.7.1.3.2 DoH along with its partner entities encourage the private sector to invest in Bioconvergence innovation projects, especially those endorsed by DoH based on panel expert review.

3.7.1.3.3 DoH will work with its partner government bodies to work on tax benefits, risk-sharing mechanisms, and co-investment opportunities to attract venture capitalists and corporate funding into the Bioconvergence field.

3.7.1.4 Professional Networks, Associations, Conferences and Scientific Events:

3.7.1.4.1 DoH will work with its partner institutions, government bodies and sectors on hosting and participation in international Bioconvergence conferences, research symposiums, and technology expos to showcase advancements, exchange knowledge, and build strong industry connections.

3.7.1.4.2 DoH will also work with its partner institutions to provide opportunities for developers of Bioconvergence innovations to actively participate in international and local forums, networks and associations.

3.7.1.4.3 DoH will work on supporting academic-industry collaborations to elevate the global reputation of national Bioconvergence initiatives

3.7.1.5 Intellectual Property (IP) and Knowledge Regulatory and Management Systems:

3.7.1.5.1 DoH will work with other concerned authorities to strengthen IP regulations and their effective implementation.

3.7.1.5.2 DoH will work with the concerned authorities to facilitate the IP registrations for researchers, startups and emerging Bioconvergence companies.

3.7.1.5.3 DoH will work on supporting copyrights through promoting scientific research through publications in high-impact journals.

3.7.1.6 Knowledge Sharing and Collaboration Platforms

3.7.1.6.1 DoH will work on developing both physical and digital collaboration hubs where researchers, industry professionals, and regulatory bodies can interact, share knowledge, and fast-track the development of Bioconvergence projects.

3.7.1.6.2 Encouraging the establishment of international knowledge and data-sharing initiatives, ensuring that Bioconvergence research is transparent, ethically conducted, and aligned with international security and privacy laws.

3.7.1.7 Other Policies and regulations impacting Bioconvergence success:

3.7.1.7.1 DoH is committed to advocate for supportive policy and regulation that facilitate the translation of Bioconvergence research into clinical practice.

3.7.1.7.2 Harmonize regulatory frameworks.

3.7.1.8 Public Awareness: Engage in public to raise awareness about Bioconvergence solutions.

3.7.2 Talent Attraction and Development:

DoH will work with its partner institutions and stakeholders to open venues and life conditions to attract talents and innovators to advance Bioconvergence innovation through the following strategies but not limited to:

3.7.2.1 Talent Networks.

3.7.2.2 Lifestyle support systems for talents.

3.7.2.3 Visa and other enhancements.

3.7.2.4 Academic institutions program enhancement & Investment in education and workforce development of current talents in the Emirate.

3.7.2.5 Capacity building and knowledge exchange

3.7.3 International Recognition:

Seeking international recognition for Bioconvergence capabilities within Abu Dhabi Emirate is key to advance this type of innovation, in this regard:

3.7.3.1 DoH will work with concerned authorities to improve visibility for Abu Dhabi based Bioconvergence.

3.7.3.2 DoH will support establishing platforms for Regulatory Collaborations as a key concept for bridging gaps in evaluation and availability of regulatory expertise in this area.

3.7.3.3 DoH demands all Abu Dhabi based Bioconvergence research and innovation to follow international regulatory standards starting from early phases.

3.8 Bioconvergence Regulatory considerations across stages in Innovation Lifecycle

3.8.1 As outlined in Section 3.4.3, this part of the policy framework is designed to articulate targeted policy actions across each stage of the Bioconvergence innovation lifecycle. Recognizing that Bioconvergence spans a complex, interdisciplinary pathway—from early discovery to market deployment.

3.8.2The distinct stages of innovation that are considered in this policy are mentioned in section 3.4.3.3.

8.3 Annex 2 presents the DoH's strategic approach to governance and details the required actions per stage of Bioconvergence innovation as per above. It also provides direction for the expected DoH support, and oversight at every critical juncture within each stage.

3.9 DoH Panel Review and Support

DoH recognizes the critical importance of providing early-stage support to foster the development of transformative Bioconvergence solutions that address high-impact healthcare challenges. In line with international innovation support frameworks, DoH in partnership with other concerned bodies, academia and funding agencies will offer scientific, regulatory, and financial support throughout the innovation lifecycle—starting from early ideation through to clinical deployment and commercialization.

3.9.1 Bioconvergence Expert Panel

3.9.1.1 DoH, in collaboration with partner regulatory bodies and other concerned entities, will establish a Bioconvergence Expert Panel to be called for support on Ad-hoc Basis to review proposals, provide early scientific advice, and recommend tailored support mechanisms.

3.9.1.2 The panel serves as a formal platform for dialogue between innovators / developers and regulatory experts, aimed at de-risking development and accelerating regulatory and market readiness.

3.9.1.3 The Multidisciplinary Bioconvergence Expert Panel will comprise local and international subject matter experts, in accordance with the submitted solutions nature including:

3.9.1.3.1 Clinical and scientific experts
3.9.1.3.2 Regulatory specialists in advanced therapies and medical technologies
3.9.1.3.3 Legal and ethical advisors
3.9.1.3.4 Data governance and AI specialists
3.9.1.3.5 Regulatory Experts & Representatives from international / Regional /Local regulatory agencies (if possible)
3.9.1.3.6 Scientists representing the relevant Omics field.

3.9.1.4 The panel's responsibilities include:

3.9.1.4.1 Providing early scientific and regulatory advice

3.9.1.4.2 Evaluating clinical/performance assessment pathways

3.9.1.4.3 Advising on clinical trial designs and evidence-generation strategies

3.9.1.4.4 Ensuring regulatory alignment with international standards (e.g., ICH, ISO, GHTF)

3.9.1.5 Review Process and Transparency:

3.9.1.5.1 Proposals passing the initial screening and deemed promising in terms of impact and feasibility will be invited to undergo Panel Review.

3.9.1.5.2 Transparency and completeness of proposals are critical scoring criteria.

3.9.1.5.3 The review outcome may result in one or more of the following:

3.9.1.5.3.1 Approval of the proposal for further development

3.9.1.5.3.2 Access to data under DoH or partner governance through formal data licensing

3.9.1.5.3.3 IRB/Ethical approval, if applicable

3.9.1.5.3.4 Request for revision and resubmission, with specific guidance provided

3.9.1.6 Additional Provisions

3.9.1.6.1 Developers must demonstrate awareness of applicable legislation and regulatory requirements, such as GMP, GCP, and GLP, depending on the nature of the innovation (e.g., a biotech product, digital therapeutic, or medical device).

3.9.1.6.2For high-risk medical devices or diagnostics, the panel will collaborate with specialized evaluators to support conformity assessment and facilitate market entry.

3.9.1.6.3 Registered SMEs may request briefing meetings with DoH / Multidisciplinary Panel to discuss their regulatory strategy and evidence-generation plans.

3.9.2 Technology Readiness Level (TRL)[8, 13,14]

3.9.2.1 Technology readiness levels (TRL) are a type of measurement system used to assess the maturity level of a particular technology. A technology project is evaluated against the parameters for each technology level and can then be assigned a TRL rating based on the project's progress. There are nine technology readiness levels. TRL 1 is the lowest and TRL 9 is the highest.

3.9.2.2 The TRL levels and definitions are as follows:

3.9.2.2.1 TRL 1: basic principles observed and reported.

3.9.2.2.2 TRL 2: technology concept or application formulated.

3.9.2.2.3 TRL 3: analytical and experimental critical function or characteristic proof-of-concept

3.9.2.2.4 TRL 4: technology basic validation in a laboratory environment

3.9.2.2.5 TRL 5: technology basic validation in a relevant environment

3.9.2.2.6 TRL 6: technology model or prototype demonstration in a relevant environment

3.9.2.2.7 TRL 7: technology prototype demonstration in an operational environment

3.9.2.2.8 TRL 8: actual technology completed and qualified through test and demonstration.

3.9.2.2.9 TRL 9: actual technology qualified through successful mission operations.

3.9.3 Support Mechanisms

Support mechanisms will be available to eligible Bioconvergence initiatives based on their Technology Readiness Level (TRL). Stage Specific support can take more than one form / channel, as listed here but not limited to:

3.9.3.1 TRL 1–3 (Early Research):

3.9.3.1.1 Scientific advice and regulatory orientation
3.9.3.1.2 Research design alignment with compliance requirements (e.g., GLP, biosafety, biosecurity, responsible research,etc.)
3.9.3.1.3 Access to academic mentors and incubators
3.9.3.1.4 Guidance on ethics and data governance

3.9.3.2 TRL 4–6 (Prototype & Preclinical Development):

3.9.3.2.1 Preclinical testing strategy support
3.9.3.2.2 Regulatory gap assessment and compliance planning (e.g., GCP, GMP)
3.9.3.2.3 Access to shared infrastructure, testing facilities, and datasets under DoH or partners' governance.
3.9.3.2.4 Eligibility for research grants and targeted tax incentives.
3.9.3.2.5 Advice on reaching out to the Relevant entities to support IP strategy development and prototype validation frameworks.

3.9.3.3 TRL 7–9 (Clinical Validation & Market Readiness):

3.9.3.3.1 Clinical trial protocol assessment and support for IRB submissions
3.9.3.3.2 Engagement with clinicians and ethics/legal advisors
3.9.3.3.3 Support with conformity assessments for medical devices and diagnostics
3.9.3.3.4 Work with regulatory agencies for Regulatory fast-track pathways, when applicable.
3.9.3.3.5 Advice on access to clinical research networks, payer input or health economic modeling services

3.9.4 Funding and Incentives

3.9.4.1 Funding for panel-reviewed proposals will be allocated through competitive grant awards. Priority inclusion in fast-track regulatory programs.

3.9.4.2 Approved projects may also be eligible for:

3.9.4.2.1 Research & Innovation Grants

3.9.4.2.2 Access to DoH-supported incubators or test beds

4. Policy Roles and Responsibilities

Stakeholder name	Stakeholder Key Role
Institutions: Health life sciences industry facilities and research centers including specialized clusters	• To ensure compliance with licensing requirements as relevant to activities • To ensure compliance with applicable regulatory standards • To foster innovation within responsible research framework • To ensure compliance with high standards quality and biosafety -Biosecurity
Inventors/startups/consortia	• To pursue organizational excellence principles • To ensure compliance with licensing requirements as relevant to activities • To ensure compliance with applicable regulatory standards
Researchers	• To comply with responsible research • To adhere to submitted and approved proposals and ensure timely updates
Funders/Investors	• To foster innovation within responsible research framework • To reward the researchers and startups for innovation • To drive a knowledge-based economy
Regulators	• To foster innovation within responsible research framework • To enable dynamic governance that evolves with scientific advancement and societal needs. • To streamline regulatory pathways providing regulatory predictability and reduce time-to-market without compromising safety efficacy and access. • To promote cross-sectoral collaboration: • To clarify responsibilities and ensure synergy among innovators, regulators, healthcare providers, and patients
Healthcare professionals and providers	• To comply with responsible research • To adhere to submitted and approved proposals and ensure timely updates
IP regulators	• To foster innovation through accessible patent filing support mechanisms
Scientific and Innovation Collaboration platforms	• To foster innovation within responsible research framework • To offer secure space for innovators and the health life science industry to explore ideas, develop concepts and discuss partnerships. • To provide funding opportunities for developers granted approvals for Bioconvergence proposals

5. Policy Scope of Implementation

The policy concerns the following:

5.1 Individuals involved in Bioconvergence Initiatives & Bioconvergence innovation projects.

5.1.1 Researchers

5.1.2 Inventors

5.1.3 Healthcare Professionals involved in Bioconvergence research

5.2 Entities involved in Bioconvergence Initiatives & Bioconvergence innovation projects.

5.2.1 Academia

5.2.2 Research Centers

5.2.3 Startups

5.2.4 Companies

5.2.5 Hospitals & clinics involved in Bioconvergence research

5.3 Regulatory Authorities:

5.3.1 Department of Economic Development

5.3.2 Authorities regulating Investment

5.3.3 Authorities regulating IP

5.3.4 Advanced Industry and Innovation Ministry

The scope of the implementation of the policy: All stages of Bioconvergence Research and Innovation in Abu Dhabi Emirates and the outcome of Bioconvergence innovation whether discovery or new information closing knowledge gap, products or solutions to healthcare challenges.

6. Exempted from Policy Scope

The following are the cases to which the policy does not apply:

6.1 Products That utilize AI and Bioconvergence research already granted internationally recognized approved.

6.2 Startups and Entities not residing or having a representation in Abu Dhabi.

6.3 Research and development that don't meet the full definition of Bioconvergence.

7. Enforcement and Compliance (Consequences/sanction of not applying policy by related stakeholder)

7.1 In the event of non-compliance with the application of the terms of this policy, examples are:

7.1.1 Submission of false or incorrect data, falsified certificates, misleading information

7.1.2 Being nontransparent with AI models or breaching AI policies

7.1.3 Breaching data security, confidentiality and integrity

7.1.4 Incompliance with biosafety, bio security and responsible research principles

7.1.5 Demonstrating serious deviation from and disrespect for organizational excellence requirements

7.1.6 Not abiding with the funding terms or the proposed Bioconvergence project plan or details

7.1.7 Exposing patients for undeclared risks, manipulation, and other ethical breaches.

7.2 The violators, whether members of the research team, the management of the facilities they are affiliated with will be subject to legal consequences such as but not limited:

7.2.1 Withdraw / cancellation of the approvals issued so far.

7.2.2 Suspending the project

7.2.3 Cancellation of the funding

7.3 The above penalties don't compromise any legal actions taken in case of criminal attempts or actions.

7.4 DoH may impose sanctions and penalties concerning any breach and /or non-compliance under this Policy in accordance with the disciplinary regulation of the healthcare sector.

9. Relevant Reference Documents

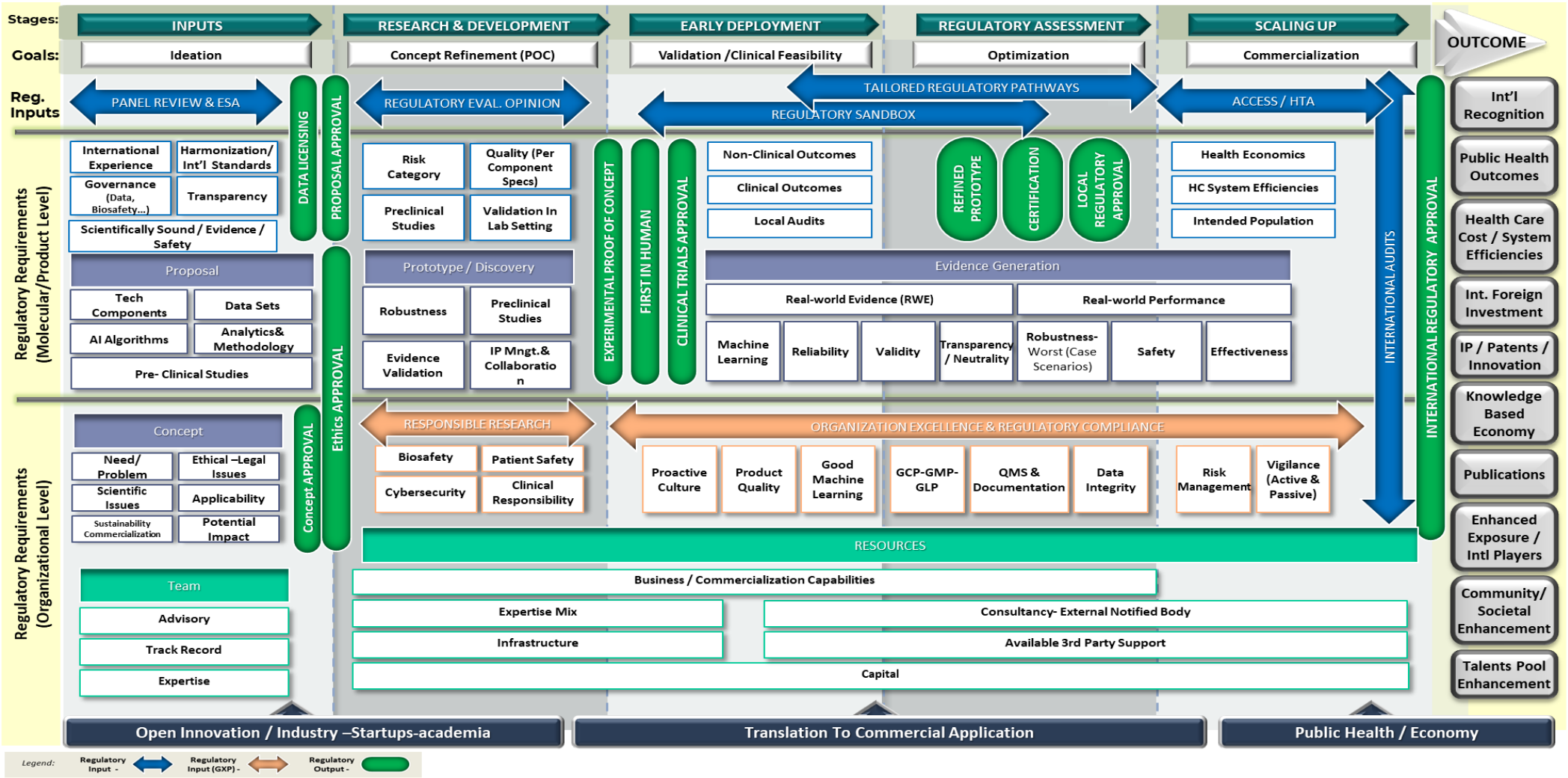
No.	Reference Date	Reference Name	Relation Explanation / Coding / Publication Links
1	2023	What is Bioconvergence	https://www.weforum.org/stories/2023/01/future-of-science-bioconvergence-davos2023/#:~:text=approach%20to%20science.,%27Bioconvergence%27%20brings%20together%20experts%2C%20processes%2C%20and%20technologies%20across,supply%20chains%20across%20multiple%20industries.
2	2022	A comprehensive insight into bioconvergence tendencies in the US and Israel.	https://www.bing.com/ck/a?!&&p=069d65284e420fac6a0ec8a0770616fa3cd7c1e1b94d9ef5cc8762d12718ecbeJmltdHM9MTc2NTE1MjAwMA&ptn=3&ver=2&hsh=4&fclid=06ec0a49-3db2-6c22-2d8c-1cf53c986d69&psq=Report%3a+A+comprehensive+insight+into+bioconvergence+tendencies+in+the+US+and+Israel.&u=a1aHR0cHM6Ly9pY2RrLmRrLy0vbWVkaWEvd2Vic2l0ZXMvaWNkay9sb2NhdGlvbnMtcmVwb3J0cy9ib3N0b24vYmlvY29udmVyZ2VuY2Utc

3	2024	*Emerging Biotechnologies in Europe: Foresight for Policy,* European Commission: Joint Research Centre, R. Lowe, C., Minssen, T. and Skentelbery, C., editor(s). Pelissier. P.-M.	https://data.europa.eu/doi/10.2760/4814109,JRC139415
4	2020	The Bio Revolution: Innovations transforming economies, societies, and our lives	https://www.bing.com/ck/a?!&&p=2d0fffbdbd5650e34114916346243b7f86f439923112f207708623a13df23064JmltdHM9MTc2NTE1MjAwMA&ptn=3&ver=2&hsh=4&fclid=06ec0a49-3db2-6c22-2d8c-1cf53c986d69&psq=The+Bio+Revolution%3a+Innov
5	2020	WHO: What is dual use research of concern	https://www.who.int/news-room/questions-and-answers/item/what-is-dual-use-research-of-concern
6	2022	WHO: Global guidance framework for the responsible use of the life sciences	https://www.who.int/publications/i/item/9789240056107
7	2025	Domaine d'Intérêt Majeur (DIM): BioConvergence pour la Santé	Regional health innovation – https://bioconvs.org/fr/home
8	2025	EIT Health: A Framework for Innovation in Healthcare	EU healthcare innovation – https://eithealth.eu/a-framework-for-innovation-in-healthcare/
9	N/A	CIMIT (Consortia for Improving Medicine with Innovation & Technology)	Medical innovation platform – https://www.cimit.org/
10	2022	Ellwood, Williams, Egan: Crossing the valley of death	Healthtech innovation process – https://www.sciencedirect.com/science/article/abs/pii/S0166497218306023?via%3Dihub https://www.sciencedirect.com/science/article/abs/pii/S0166497218306023
11	2022	Ritter & Pedersen: An Entrepreneur's Guide to Surviving the "Death Valley Curve"	https://hbr.org/2022/04/an-entrepreneurs-guide-to-surviving-the-death-valley-curve
12	2022	Gbadegeshin et al.: Overcoming the Valley of Death	Startup success model – https://www.sciencedirect.com/science/article/pii/S2666188822000119?via%3Dihub https://doi.org/10.1016/j.sftr.2022.100077
13	2025	UK Research and Innovation: TRL Eligibility	TRL funding guidance – https://www.ukri.org/councils/stfc/guidance-for-applicants/check-if-youre-eligible-for-funding/eligibility-of-technology-readiness-levels-trl/

14	2025	NIH: Technology Readiness Levels	Tech maturity assessment – https://ncai.nhlbi.nih.gov/ncai/resources/techreadylevels
15	N/A	US FDA: Adaptive Designs for Clinical Trials	Adaptive trial guidance – https://www.fda.gov/media/78495/download
16	2020	Bhatia et al.: Hybrid clinical trials to generate real-world evidence	Hybrid trial methods – https://www.sciencedirect.com/science/article/abs/pii/S1551714419305713
17	2023	Holzinger et al.: AI for life: Trends in artificial intelligence for biotechnology	AI trends in biotech – https://www.sciencedirect.com/science/article/pii/S1871678423000031
18	2023	US FDA: Proposed Regulatory Framework for AI/ML-Based SaMD	AI/ML device regulation – https://www.fda.gov/files/medical%20devices/published/US-FDA-Artificial-Intelligence-and-Machine-Learning-Discussion-Paper.pdf
19	2021	US FDA: Good Machine Learning Practice for Medical Device Development	GMLP principles – https://www.fda.gov/media/153486/download
20	2023	Watson et al.: FDA regulations and prescription digital	Digital therapeutics regulation – https://doi.org/10.3389/fdgth.2023.1086219
21	2020	O'Brien & Nelson: Assessing the Risks Posed by AI and Biotechnology Convergence	AI-biotech risk assessment – https://doi.org/10.1089/hs.2019.0122
22	2023	Nuclear Threat Initiative (NTI): The Convergence of AI and Life Sciences	AI/life sciences governance – https://www.nti.org/wp-content/uploads/2023/10/NTIBIO_AI_FINAL.pdf
23	2021	National Intelligence Council: Structural Drivers of the Future	https://www.dni.gov/index.php/gt2040-home/gt2040-deeper-looks/future-of-biotech
24	2024	ECA: Living guidelines on responsible use of generative AI	https://european-research-area.ec.europa.eu/news/living-guidelines-responsible-use-generative-ai-research-published
25	2025	IDRMF:Good-machine-learning-practice-medical-device-development-guiding-principles	International GMLP guidance – https://www.imdrf.org/
26	N/A	Dassault Systèmes: What is a Virtual Twin in Healthcare?	Virtual twins in healthcare – https://www.3ds.com/virtual-twin/life-sciences-

10. Appendix

Appendix 1: Conceptual Framework for Bioconvergence P



Annex 1: Risk Based approach towards most important Bioconvergence Applications in Health Life Sciences:

This annex is an integral part of DoH's "Health Life Sciences Bioconvergence Policy"

1. General

Generally [4, 21]: Bioconvergence as an approach for surge of innovation in biology carries profound and unique risks and issues. These risks introduce a unique set of considerations which, if not managed properly, could potentially outweigh the promised benefits:

1.1. Biology is self-replicating, is self-sustaining, and does not respect jurisdictional boundaries. For example, new genetically engineered gene drives applied to the vectors can be difficult to control and can potentially do permanent damage to ecosystems.

1.2. The interconnected nature of biology can increase the potential for unintended consequences. Changes to one part of a system can have cascading effects and unintended consequences across entire ecosystems or species.

1.3. Low barriers to entry for dual-use technologies, such as access to commercial CRISPR kits, 3D printing and others, potentially leading to harmful or unintended outcomes, raise significant concerns and need to be addressed.

1.4. Forging consensus among more than one value system is challenging —at the individual, cultural, societal, academic and national levels.

1.5. Unequal access could perpetuate socioeconomic disparity, with potentially regressive effects.

1.6. Data and bio-specimen misuse/dual use without compliance with ethical and data privacy regulations

2. Application specific Risks [23]:

The integration of diverse scientific disciplines through Bioconvergence is driving a new wave of innovation in healthcare, offering groundbreaking applications that enhance disease prevention, diagnosis, treatment, and patient care. Some of these applications are mentioned here highlighting main risks that need consideration when studying applications:

2.1 Digital Healthcare and Precision Medicine:

Healthcare professionals, diagnostic technologies, wearables, and Internet of Everything (IoE) devices are generating an increasing amount of health data. When combined with other personal information, digital behavior records, and cyber indicators, this data can significantly improve the prediction of new diseases and treatment outcomes. However, such extensive data aggregation may jeopardize both physical and digital anonymity, potentially allowing some parties to target or discriminate against individuals based on their biosignatures, current or anticipated health conditions, or inferred genetic characteristics.

2.2 Bioprinting of Organs and Other Individualized Therapies:

Bespoke genetic and cellular therapies are already available for some conditions, though at high cost. Their scope is expected to expand, including tissue printing. While expensive, they may be more cost-effective than long-term chronic disease management. However, widespread access may remain limited in the foreseeable future, raising concerns about healthcare equity.

2.3 Reproductive Engineering:

Enhance Human Traits and Performance Advancements in technology now allow screening, selection, and potential genetic modification of human embryos. Initially, efforts will focus on preventing health issues and selecting physical traits, but as costs drop and reliability improves, demand for trait selection may rise. Modifications for traits like height, eye color, and possibly intelligence could become feasible. However, these practices may deepen ethical divides, remain inaccessible to many, or even be mandated in some societies, raising concerns about inequality.

2.4 Biomachine Interfaces including Computer -Human Interfaces:

Biomachine interfaces a field of biology defined as the connection of nervous systems

of living organisms to machines, including in brain-machine interfaces [22].

Advancements in human-machine integration are enhancing medical treatments, particularly for neurological conditions. Non-invasive technologies, such as electroencephalographs, neural stimulators and electrical or magnetic transmitters enable many medical uses through stimulation and detection of brain activities. Such technologies marginally improve perception, memory, and attention. Invasive brain-computer interfaces, already used to treat neurological disorders, are currently limited by low data-transfer rates. Emerging systems may significantly enhance cognitive and sensory functions, offering breakthroughs in treating paralysis, neurodegenerative diseases, and sensory impairments.

While human-machine integration holds great medical promises, it also presents significant ethical challenges:

2.4.1 Privacy and data security risks include the vulnerability of brain data to hacking,
unauthorized tracking, and potential misuse by third parties such as insurers or employers.

2.4.2 There are concerns that altering or augmenting neural processes could inequality, and human dignity concerns if neural interfaces influence thoughts or decion- making.

2.4.3 Unintended psychological and social consequences include mental health risks,
cognitive enhancement, raising philosophical and legal questions about personhood and consent

2.4.4 Ethical considerations also extend to vulnerable populations, such as children, the elderly, or disabled individuals, who may face coercion or unintended consequences of neural interventions.

2.4.5 Regulatory oversight is critical to prevent corporate control, ensure responsible governance, and address international disparities in access and ethical use.

2.4.6 Ensuring transparency, patient autonomy, robust security, and equitable access will be critical in shaping responsible development and use of these technologies. application of these technologies, transparency, patient autonomy, robust security, and equitable access must be prioritized.

2.5 Biotechnology/ Biomanufacturing Materials and Devices (Engineering Biology) [3]:

Automation and data-driven processes are increasingly being incorporated into biotechnology and anticipated to radically improve the predictability and reproducibility of research and manufacturing outcomes. Industrial biotechnology is transforming how industries produce energy, materials, food, and pharmaceuticals, offering innovative solutions to some of the most pressing global challenges. By integrating biological processes with cutting-edge technologies like AI, robotics, and genetic engineering, this sector is poised to play a critical role in achieving sustainability goals, fostering economic resilience, and driving growth in the bioeconomy [3]. Automated molecular assembly techniques with DNA and other biomolecules probably will push engineering and design capabilities further into the nanoscale application space, hastening the convergence of biological and digital technologies. Genetic modification may enable production, enhance or tailor output in precision medicines production. However, Biosafety and Biosecurity risks need special attention.

2.6 Biocomputing and DNA-Based Data Storage:

2.6.1 Biocomputing in terms of using cells and cellular components for computation. Include the DNA to encode and store data is already technically feasible and being demonstrated in laboratories. DNA or similar chemical polymers probably will be used to store data for archival purposes in future. Such use of synthetic DNA offers unmatched storage capacity, durability, and low energy consumption, making it a potential medium for long-term medical data preservation within the next two decades. [22]

2.6.2 Medical applications include storing patient genomes, tracking disease progression, archiving biomedical research, and preserving drug development data could revolutionize personalized medicine, epidemiological studies, and AI-driven healthcare analytics. They could also enable new forms of long-term social monitoring, stimulating capabilities that could be used to control as well as protect.

2.6.3 Risks Involved in Biocomputing and DNA-Based Data Storage that need to be considered:

2.6.3.1 Technical complexity and reliability can lead to difficulties in ensuring consistent and reliable performance. DNA synthesis and sequencing processes can introduce errors, affecting data integrity and retrieval accuracy.

2.6.3.2 Scalability and Cost: Current technologies for DNA data are still in the experimental stage, storage are not yet scalable for widespread commercial use. The cost remains high, making it an expensive option compared to traditional data storage methods.

2.6.3.3 Data Security and Privacy Risks: As with any data storage technology, there are concerns about data security. Privacy Concerns: Handling biological data raises privacy issues, particularly if the data is derived from human DNA.

2.6.3.4 Environmental impact: The processes involved in DNA synthesis and sequencing can have environmental impacts, which need to be managed responsibly.

2.6.3.5 Ethical Consideration: The use of biological materials for data storage raises ethical questions, particularly regarding the manipulation of genetic material.

2.6.3.6 Regulatory and Standardization Challenges: The lack of established regulatory frameworks for biocomputing and DNA data storage can pose challenges in terms of compliance and Governance. Additionally, the absence of industry standards can hinder interoperability and the development of universally accepted practices.

2.7 Manage, cure or eradication of Many Diseases:

Eradication of most common diseases may be possible, spurred on by a range of biotech advances, including disease vector control and the development of new medical treatments and preventive medicines. Global efforts to address contagious and deadly maladies, such as malaria or tuberculosis, could offer significant improvements in productivity, quality of human life, and longevity.

2.7.1 Inequitable Access: Despite scientific progress, real-world application is often constrained by uneven global access to advanced technologies and treatments.

2.7.2 Prioritization Disputes: Determining which diseases to target for elimination is subject to ethical, economic, and geopolitical debate, often influenced by market forces rather than public health need.

2.7.3 Infrastructure Gaps: Low-resource settings may lack the health systems, data infrastructure, or distribution networks required for implementation.

2.8 On-Demand Medicine Production:

2.8.1 The capability to rapidly produce treatments and vaccines could be a game-changer for responding to natural and engineered pandemics. However, ensuring secure, scalable, and equitable access remains a challenge, as well as preventing misuse or bioterrorism risks.

2.8.2 Regulatory attention needed for the following areas:

2.8.2.1 Safeguards against the misuse of rapid biomanufacturing, rapid and compromised regulatory evaluation.

2.8.2.2 Safeguards and mechanisms in place for pots authorization follow up, Pharmacovigilance, completion of phase 3 clinical studies and conduct of phase 4 safety studies.

2.8.2.3 Scalability and affordability of on-demand production.

2.8.2.4 Secure supply chains for critical medicines.

2.9 Synthetic Biology:

The ability to create living, reproducing synthetic organisms with expanded genetic codes could revolutionize biotech research, and medicine.

These advancements could accelerate drug discovery, bio-based manufacturing, and environmental solutions. However, they also raise ethical, safety, and security concerns regarding unintended ecological consequences, biosecurity risks, and potential misuse [21,22].

The introduction of never-before-seen organisms could fuel debates on scientific oversight, regulatory controls, and equitable access to benefits.

While offering significant advancements in medicine, agriculture, and industry, it also presents various risks that require careful consideration [3]:

2.9.1 Biosafety hazards: The manipulation of biological systems can lead to unintended consequences, including the creation of novel pathogens or toxins. Accidental release of genetically modified organisms (GMOs) may pose health risks to laboratory personnel and the public.

2.9.2 Biosecurity threats: Advancements in bioengineering have lowered the barriers to creating or modifying organisms, raising concerns about the potential misuse of these technologies for bioterrorism or biological warfare.

2.9.3 Environmental impact: The release of engineered organisms into the environment can disrupt ecosystems, lead to loss of biodiversity, and result in horizontal gene transfer to native species.

2.9.4 Ethical and societal implications: The creation and manipulation of life forms raise ethical questions about the extent of human intervention in nature and the potential for unforeseen societal consequences.

2.9.5 Cyber-biosecurity risks: The digitization of biological research introduces vulnerabilities, such as the potential for cyberattacks that manipulate DNA sequences to produce harmful biological agents.

2.10 Xeno-Bioengineering:

Xeno-bioengineering refers to the modification and application of biological materials, genes, cells, tissues, or organs derived from non-human species, particularly animals, for use in human biomedical applications, such as Xenotransplantation (e.g., transplanting genetically modified pig hearts into humans),cross-species gene editing and animal-to-human synthetic biological interfaces. While these technologies offer potential to address organ shortages and advance regenerative medicine, several risks must be considered:

2.10.1 Zoonotic disease transmission: The use of animal tissues increases the risk of transmitting unknown or latent pathogens to humans, including porcine endogenous retroviruses (PERVs) in pigs.

2.10.2 Immunological rejection and chronic inflammation: Despite genetic editing (e.g., knockout of key antigens such as organs α-Gal), animal organ often elicit immune response that may require lifelong immunosuppression, increasing the risk of infection, malignancy, and metabolic complications.

2.10.3 Ethical and cultural sensitivities: Use of animal parts in humans raises ethical issues, particularly in communities where certain animals are sacred or consumption is restricted (e.g., pigs, cows).

2.10.4 Genetic cross-species blurring: Genetic engineering that combines human and animal genes (e.g., humanizing pigs) leads to blurred species boundaries, raising long-term ethical and safety concerns.

2.10.5 Regulatory gaps: Current biosafety bioethics and medical device regulations may not fully cover genetically engineered animal-derived products, leading to oversight challenges.

DoH Health Life Sciences Bioconvergence Policy

Annex 2: Stage wise regulatory approach -Bioconvergence Innovation Life Cycle.

This annex is an integral part of DoH's "Health Life Sciences Bioconvergence Policy"

As outlined in Section (6.3), this part of the policy framework is designed to articulate targeted policy actions across each stage of the Bioconvergence innovation lifecycle. Recognizing that Bioconvergence spans a complex, interdisciplinary pathway—from early discovery to market deployment, this section presents the DoH's strategic approach to governance, support, and oversight at every critical juncture.

1. Stage 1 "Ideation, Concept & Proposal Development":

This stage marks the foundation of Bioconvergence innovation, where novel ideas emerge at the intersection of disciplines. At this early stage, a clear policy and governance framework is essential to guide responsible innovation, align emerging concepts with public interest, and ensure early consideration of ethical, regulatory, and societal implications. Without such oversight, there is a risk of pursuing concepts that may be scientifically unsound, ethically questionable, or misaligned with long-term safety and public trust.

1.1 Bioconvergence Policy Success Goals for the "Ideation, concept and proposal development" stage:

1.1.1 Encourage creativity while setting foundational, ethical and scientific expectations.

1.1.2 Facilitate transition to the next phase "Research and Development" phase.

1.1.3 Maximize the potential of the next stages: A robust proposal (scientific, ethical and business) leads to regulatory compliant and commercially viable product/solution or a discovery that can shape medical practice.

1.2 Substages: This stage, from a regulatory perspective, should follow the following three distinct substages:

1.2.1 Team formation

1.2.2 Concept Development

1.2.3 Proposal Development for funding and granting regulatory approval to kick off the Research and Development Stage.

1.3 **Team Formation:** The Team is a cornerstone of successful Bioconvergence ideation and concept development. The team should be composed of members demonstrating various intellectual and leadership capabilities to demonstrate the following:

1.3.1 **Talent:** Teams working on Bioconvergence innovation must be composed of talented individuals who combine scientific depth with creativity and entrepreneurial thinking. The main elements of talented team are:

1.3.1.1 Creative: ability to bring in out of box solutions

1.3.1.2 Collaborative Mindset: Teams must show openness to cross-sector collaboration, including partnerships with academia, industry, startups, and government entities.

1.3.1.3 Commitment to Impact: A clear focus on patient-centric, societal, and/or economic impact should be evident, with defined metrics for potential value creation.

1.3.1.4 Commitment to Capacity Building: Teams should be willing to engage in mentorship, talent development, and knowledge transfer, contributing to the long-term sustainability of the Bioconvergence ecosystem.

1.3.2 **Core Team** (Team Lead & Team Coordinator) should exhibit the following:

1.3.2.1 Multidisciplinary Composition: Teams should include diverse expertise spanning biology, engineering, data science, clinical research, and relevant technological domains, enabling integrated and system-level thinking.

1.3.2.2 Qualified: Team working on Bioconvergence need to be qualified in their expertise areas demonstrated by graduate & postgraduate degrees (Ph.D., M.S., or B.S.) in relevant fields such as Biology, Biotechnology, Bioinformatics, Biomedical Engineering, Computer science, Data Science, or related disciplines.

1.3.2.3 Expertise: Team may have extensive experience in research and development within the biotech or pharmaceutical industries, or experience in interdisciplinary projects that combine biology with technology, such as computational biology, systems biology, or synthetic biology.

1.3.3 **Track Record:** Team should show a detailed and clear proven track record of:

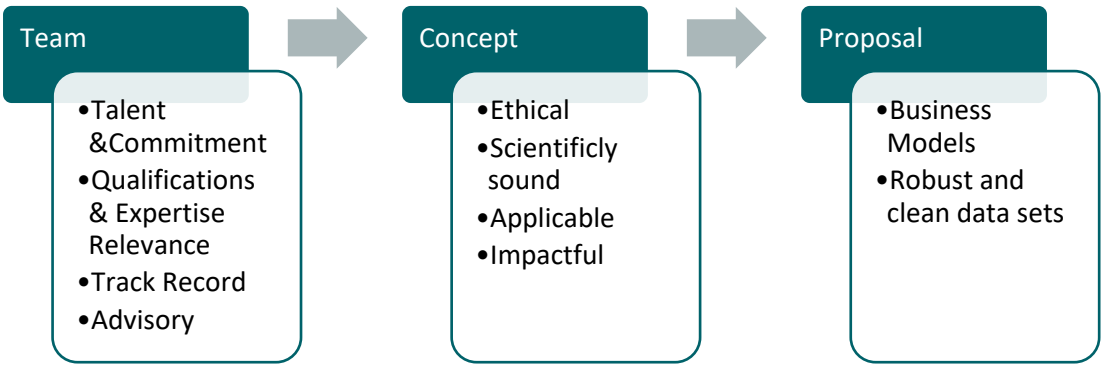
1.3.3.1 Working with reputable organizations or institutions or collage.

1.3.3.2 Past projects that the team has completed successfully, including the objectives, outcomes, and any notable achievements.

1.3.3.3 Research proven by published research papers, articles, and studies in reputable journals, showcasing the team's contributions to the scientific community.

1.3.3.4 Awards, honors, or recognition(s) received by the team or its members for their work in Bioconvergence if applicable.

1.3.3.5 Collaborations with other research institutions, universities, or industry partners, demonstrating the team's ability to work effectively with others.



1.3.4 **Good standing** refers to the reputation, credibility, and overall performance of a team, organization, or individual within the field.

1.3.4.1 Having a positive reputation within the scientific and professional community, recognized for contributions to the field of Bioconvergence.

1.3.4.2 Producing high-quality research, publications, and innovations that advance the field, and demonstrating excellence in project execution and delivering impactful results.

1.3.5 **Capable Team Lead** must exhibit the following criteria:

1.3.5.1 Demonstrable track record in successfully leading multidisciplinary teams, preferably within fields relevant to the proposed Bioconvergence innovation.

1.3.5.2 Entrepreneurial Drive: The lead and core team members should exhibit strong entrepreneurial qualities, including strategic vision, initiative, and the capacity to translate novel ideas into viable, scalable solutions.

1.3.5.3 Translational Capability: The team should demonstrate the ability to bridge the gap between early-stage research and real-world application, including familiarity with regulatory pathways, IP strategy, and market dynamics.

1.3.6 **Capable Team Coordinator** needs to be appointed and should demonstrate strong project management skills, including planning, execution, and risk management.

1.3.7 **Capable** Team **Mentor/ Advisory** are strongly encouraged to engage with experienced mentors, advisors, or an advisory board comprising experts from relevant scientific, technological, and business sectors. The involvement of seasoned advisors is critical in shaping, refining, and advancing Bioconvergence initiatives to maximize their potential for success and real-world impact. Advisors serve as strategic partners, offering insights that help teams navigate complex challenges and accelerate innovation. The Key contributions of advisors include:

1.3.7.1 Strategic Guidance: Providing high-level consulting and expert advice to ensure alignment of the team's vision and projects with emerging trends, market dynamics, and broader organizational or national goals.

1.3.7.2 Innovation Stewardship: Supporting the team in setting long-term objectives, defining impactful outcomes, and identifying untapped opportunities for growth and interdisciplinary innovation.

1.3.7.3 Entrepreneurship Development: Helping shape the team's entrepreneurial mindset and strengthen their business acumen by fostering critical thinking, value creation strategies, and market-readiness.

1.3.7.4 Network Enablement: Leveraging their professional networks to introduce the team to key collaborators, potential co-development partners, funding bodies, and relevant institutions across sectors.

1.3.7.5 Stakeholder Engagement: Facilitating access to key stakeholders, including regulatory bodies, policy influencers, investors, and industry leaders, thereby accelerating the path to validation, support, and adoption.

1.3.7.6 The presence of an active, diverse, and engaged advisory structure is considered a strong asset and a key enabler for the maturity and sustainability of Bioconvergence innovation.

1.4 **The Concept:**

1.4.1 **The importance of solid concepts:**

1.4.1.1 For the ideation stage to proceed into a formal cycle of innovation and get the recognition and funding opportunities, the owners of the Bioconvergence project idea

can approach DoH- concerned section via the different platforms initiated for this purpose, submitting a well detailed concept document.

1.4.1.2 DoH will actively seek and create opportunities to engage Bioconvergence innovation teams through structured initiatives such as innovation challenges and targeted competitions. These platforms will invite multidisciplinary teams to submit their concept proposals for formal evaluation, fostering a culture of innovation and enabling early-stage ideas to gain visibility, expert feedback, and potential support. By doing so, DoH aims to identify high-potential solutions, accelerate their development, and strengthen the overall Bioconvergence ecosystem within the healthcare landscape.

1.4.1.3 Upon need, these concept proposals will be also studied by the IRB committee (refer to DoH Standard on Human Subject Research (DoH/QD/SD/HSR/0.9)).

1.4.2 "Concept Application" submission: DoH will issue detailed instructions on how concepts for Bioconvergence projects would be presented. Mainly the application should provide the following details in a clear, accurate and complete but concise manner (but not limited to):

1.4.2.1 Problem statement: clear description of the problem, its impact and causes

1.4.2.2 Description of the intended solution and its concept: Description of the basis of the work, conceptual framework on how it is expected to solve the problem, classifying the intended outcome into one of the following:

1.4.2.2.1 Discovery or closing a gap in information.

1.4.2.2.2 Solution for the heath challenges that can be of one or multi component working together in a system: here the applicant should describe these components and how they will integrate and work in synergy toward solving the problem.

1.4.2.3 Science behind the concept: provide details on how the concept will work to solve the problem and what scientific basis will be supporting the concept.

1.4.2.4 Risk Identification and Mitigation: Applicants should provide Comprehensive risk assessment along with mitigation measures.:

1.4.2.4.1 Risk Assessment: Identification of scientific, technical, ethical, regulatory, or operational risks relevant to the proposed solution. This includes potential safety concerns, data misuse, unintended consequences, or barriers to implementation.

1.4.2.4.2 Risk Mitigation Measures: Description of strategies and safeguards to prevent, minimize, or manage identified risks and to ensure responsible development and application of the innovation. This includes ethical oversight, biosafety measures, regulatory compliance, and protection against misuse or abuse.

1.4.2.5 Impact, Commercialization, and Sustainability: applicants must clearly articulate how the proposed Bioconvergence solution addresses the identified problem, including its expected impact. Where applicable, the submission should outline a feasible pathway for commercialization and describe measures that will support the long-term sustainability of the solution.

1.4.2.6 Team Composition and Multidisciplinary Collaboration:

Applicants must describe the multidisciplinary expertise and backgrounds required to advance the concept beyond its initial stage. The submission should include:

1.4.2.6.1 A brief overview of the current preliminary team composition and the proposed team structure if the concept is approved.

1.4.2.6.2 Identification of the designated team lead, including relevant qualifications.

1.4.2.6.3 Identification of the mentor or advisor, if already engaged.

1.4.2.6.4 Curriculum Vitae should be provided for the current team and the mentor.

1.4.3 Concept Review & Evaluation: The concept will be reviewed and evaluated by DoH on the basis of different criteria, the most important are:

1.4.3.1 Ethical Considerations:

1.4.3.1.1 Bioconvergence innovations must adhere to locally and internationally recognized ethical standards. Ensuring that all developments prioritize patient safety, transparency, and fairness is a key mandate.

1.4.3.1.2 Concepts will receive higher evaluation scores if the proposed solution and its components demonstrate potential to improve equitable access to Bioconvergence technologies, ensuring that advanced innovations benefit diverse populations and do not disproportionately favor specific groups while excluding others from access to cutting-edge treatments.

1.4.3.2 Risk Prevention & Mitigation: Biosafety and Biosecurity considerations: Applicants must demonstrate awareness of potential risks associated with any stage of the Bioconvergence innovation lifecycle—from ideation and development to validation and deployment. Proposals that demonstrate proactive, well-informed risk management will score higher under this criterion.

1.4.3.3 Scientific Soundness: The proposed concept must be based on scientifically credible principles, supported by existing evidence, preliminary data, or a well-articulated hypothesis grounded in current knowledge across relevant disciplines. The evaluation will consider ensuring that Bioconvergence solutions concepts in the application are based on scientific principles and address real-world healthcare challenges. The clarity and rigor of the scientific rationale need to be demonstrated for:

1.4.3.3.1 Alignment with validated theories, methodologies, or frameworks from contributing scientific fields (e.g., biology, engineering, data science, etc.).

1.4.3.3.2 The robustness of any preliminary findings or prior research, if available: Concepts lacking a coherent scientific foundation or that rely on unproven or speculative claims without justification will receive lower scores under this criterion.

1.4.3.4 Feasibility and Applicability of the approach: The appropriateness of any proposed technologies or tools of the solutions promised by the Bioconvergence concept must be evaluated for its suitability in addressing specific medical conditions or healthcare needs:

1.4.3.4.1 Ensuring that it delivers tangible benefits over existing solutions.

1.4.3.4.2 Ensuring that Bioconvergence solutions are robust, scalable, and clinically viable.

1.4.3.4.3 Application in other cases: While a Bioconvergence solution may initially be developed for a particular medical need, its potential for application in other areas shall be explored to maximize its utility and economic value.

1.4.3.4.4 Application in different settings: The feasibility of integrating Bioconvergence innovations across diverse healthcare settings including hospitals, clinics, telemedicine platforms, and home-based care must be assessed to ensure widespread accessibility and usability.

1.4.3.4.5 Patentability: The solution that imply potential for patentability and don't breach other patents are more feasible.

1.4.3.5 Emphasize multidisciplinary Collaboration and work Collaboration between research institutions, healthcare providers, industry players, and government regulators is crucial to the success of the concept. The current team composition and level of mentoring it got so far is important criterion for evaluation.

1.4.3.6 Potential Impact:

1.4.3.6.1 Patients: Bioconvergence shall drive personalized medicine, enhance treatment precision, reduce adverse reactions, and improve overall patient outcomes through AI-driven diagnostics, bioengineered solutions, and smart therapeutic systems. Advanced therapeutics, such as gene editing and regenerative medicine, could offer life-saving interventions for previously untreatable conditions. Bioconvergence innovations must be ensured that they are effectively integrated into clinical practice, with emphasis on safety, affordability, and accessibility for patients in Abu Dhabi.

1.4.3.6.2 Public Health: the concept application shall include the disease surveillance, disease burden, outbreak prediction, and pandemic response, strengthening Abu Dhabi's public health infrastructure. Bioconvergence innovations can improve early detection and prevention of diseases through biosensors, wearable devices, and AI-powered analytics. These tools can help in managing chronic diseases, reducing healthcare burdens, and enhancing population health strategies. Collaborations with public health authorities and research institutions will ensure that Bioconvergence solutions contribute to a more resilient and proactive public health system.

1.4.3.6.3 Healthcare System: the application should clarify how by integrating technology-driven solutions, Bioconvergence can streamline healthcare delivery, reduce operational costs, and improve efficiency in patient management and clinical workflows. For example: AI-driven automation in hospitals can optimize patient flow, reduce waiting times, and enhance medical decision-making. Suggested mechanisms for implementation have to be explained if applicable, to ensure that healthcare providers effectively adopt and integrate Bioconvergence solutions while maintaining high standards of care.

1.4.3.6.4 Healthcare Ecosystem: the concept should open opportunities for wider ecosystem contributions whether pharmaceutical companies, AI developers, biotech firms, and research institutions. The impact on the general Health Life Sciences Ecosystem should be demonstrated, especially in terms of positioning Abu Dhabi as a global leader in medical technology.

1.4.3.7 Innovation:

The proposal will be evaluated based on the originality and transformative potential of the proposed Bioconvergence solution. This includes the extent to which it introduces novel ideas, integrates discipline in an unprecedented way, or disrupts existing approaches in healthcare and life sciences. The evaluation will consider:

1.4.3.7.1 Novelty: The uniqueness of the concept in terms of scientific approach, technological integration, or application within the Bioconvergence domain.

1.4.3.7.2 Interdisciplinary Synergy: The extent to which the concept meaningfully combines insights and technologies from multiple disciplines (e.g., biology, engineering, data science, nanotech, etc.) to create added value.

1.4.3.7.3 Transformative Potential: The capability of innovation to significantly advance current practices, improve outcomes, or address unmet needs in a new or superior way. Concepts that represent incremental improvements without clear differentiation or innovation from the current solutions or status quo will receive lower scores under this criterion.

1.4.4 Concept Approval:

1.4.4.1 Based on the evaluation criteria outlined above, selected concepts will be granted formal approval in the form of a documented endorsement. This approval may be used by the proposing team to seek further support from funding agencies, academic institutions, and strategic partners to advance their innovation.

1.4.4.2 The approval serves as a critical enabling factor, encouraging the applicant team to develop a comprehensive project proposal, as detailed in the following section. It marks an essential step toward the structured development, validation, and potential commercialization of Bioconvergence innovations—while upholding standards of safety, efficacy, and public benefit.

1.4.5 The Proposal

1.4.5.1 Following the approval of the concept, in order to facilitate funding and regulatory applications, applicant teams are required to develop and submit a full proposal for their Bioconvergence solution. This proposal is essential to position the team for funding opportunities that will support further development, validation, and potential commercialization of their innovation.

1.4.5.2 DoH, in collaboration with partner institutions, will facilitate access to platforms and mechanisms that enhance the visibility of these proposals and increase their chances of securing funding. Given the critical importance of early-stage financing, particularly during the research and development where refinement of the idea (concept) and/ or the proof-of-concept takes place, DoH recognizes the importance of government-backed funding to bridge initial gaps and accelerate progress.

1.4.5.3 The Proposal Requirements: The proposal should build upon the elements submitted in the concept application, presenting them in a more refined, detailed, and structured manner. In addition to the original components, the proposal must include a clear plan of action, proposed timelines, and preliminary ideas for business models and commercialization pathways to demonstrate the project's feasibility and long-term impact.

1.4.5.4 The subsequent sections will outline the required structure of the proposal and key elements to be addressed in the Proposal to be endorsed by the DoH and its partners:

1.4.5.4.1 **Problem statement** and its burden: the same guidance will be followed for proposal with more detail, supported by field research and literature.

1.4.5.4.2 Detailed description of the **proposed Solution:**

1.4.5.4.2.1 Components of the Solution and their integration within the proposed solution. This section must provide a detailed description of each sub-innovation or component that forms part of the overall Bioconvergence solution. For each component, applicants should clearly outline the underlying technology, mode of action, and its specific role or contribution to improving patient care, diagnostics, treatment, or overall medical practice.

1.4.5.4.2.2 Conceptual Framework: The proposal must present a clear conceptual framework illustrating how the individual components of the Bioconvergence solution interact and integrate to form a cohesive and functional system. This section should explain how the proposed solution addresses the identified problem, the key enablers that will support its success, and what success will look like expressed through well-defined, measurable outcomes. The framework should demonstrate the synergy among components, showing how they work in harmony to deliver a unified and impactful innovation in healthcare.

1.4.5.4.3 Regulatory Alignment:

1.4.5.4.3.1 Where applicable, applicants should indicate whether components are novel, adapted from existing technologies, or require specific regulatory consideration.

1.4.5.4.3.2 Classification of Bioconvergence Solution, all proposed Bioconvergence solutions both as individual components and as an integrated system must be clearly categorized according to their intended healthcare applications (e.g., medical devices, pharmaceuticals, diagnostics, AI-driven analytics, or regenerative medicine) This classification is essential, as it will inform the applicable regulatory pathway at later stages of development. Applicants are expected to align their classification with the guidelines established by internationally recognized regulatory authorities such as the U.S. FDA, EMA, and, where applicable, local requirements issued by the Emirates Drug Establishment (EDE).

1.4.5.4.3.3 Regulatory Pathways expected Applicant teams, when applicable need to provide a preliminary outline of the expected regulatory pathways required for the proposed Bioconvergence solution to progress toward scale-up and commercialization. This includes identifying the relevant certifications, approvals, and compliance frameworks necessary to meet international regulatory standards such as those set by the FDA, EMA, ISO, and WHO. Where applicable, alignment with national regulatory requirements such as those issued by the Emirates Drug Establishment (EDE) must also be considered. Ensuring early awareness of regulatory expectations helps safeguard the solution's quality, safety, efficacy, and ethical integrity, and is critical for verifying that the innovation is reliable, secure, and ready for responsible deployment.

1.4.5.4.4 **Impact on the full Ecosystem**: The proposal must assess the combined impact of the full Bioconvergence solution in terms of its clinical relevance,

innovation value, and translational potential. As introduced in the concept stage, impact should be considered across multiple dimensions including benefits to patients, public health outcomes, improvements to the healthcare system, and contributions to the broader health and life sciences ecosystem. Additional dimensions such as economic value, knowledge generation, and societal advancement may also be highlighted where applicable. A clear articulation of these impacts will strengthen the proposal's case for support and long-term viability.

1.4.5.4.5 **Data Sources and Evidence Base**: Bioconvergence Innovation start with Data collection or use of existing Data and its processing at multiple levels, from raw sequences (genomics, imaging) to primary clinical trial data and secondary aggregated reports used for AI training and meta-analysis. For proposals involving the use of primary data (e.g., data collected directly through clinical studies, patient monitoring, or user engagement) or secondary data sources (e.g., electronic medical records, registries, databases, or previously collected research data), a robust data strategy is essential to ensure scientific credibility, regulatory alignment, and ethical integrity. This applies across all use cases —including data mining, advanced analytics, observational research, AI-driven models, digital health tools, or clinical research components. Applicants must clearly describe the origin, nature, and use of data supporting their innovation and address the following key elements:

1.4.5.4.5.1 Reliable Source of Data: The source of data must be from reliable, validated, local data and if it is sourced internationally, it should be from a recognized health database, government registries, and clinical research centers. Data sources must be independently verified and comply with international data governance frameworks to maintain integrity and trust to ensure reliability.

1.4.5.4.5.2 Data Relevance and Scientific Validity: Data must be directly related to the clinical or scientific problem being addressed and sourced from reliable and validated repositories. Acceptable data types may include —but are not limited to— electronic health records (EHRs), real-world evidence (RWE), clinical trial data, imaging datasets, multi-omics data (genomics, proteomics, etc.), wearable device data, and patient-reported outcomes.

1.4.5.4.5.3 Regulatory and Ethical Compliance: All data use must adhere to local and international data privacy regulations such as ADHICS, GDPR and HIPAA. Use of human data requires documented informed consent, institutional approvals, and compliance with ethical review processes. Informed consent forms shall clearly state how personal and biological data will be used, stored, and shared, including for analytics or AI-driven insights. Mechanisms must be in place to allow data subjects to exercise their rights to access, correction, withdrawal of consent, and data erasure in line with UAE PDPL.

1.4.5.4.5.4 Transparency and Explainability: Especially for AI and machine learning applications, applicants must describe data acquisition, preprocessing methods,

labeling/annotation strategies, and any data curation processes. Explainability of data use should be evident to support trust and interpretability of results.

1.4.5.4.5.5 Representativeness and Bias Mitigation: Data should be diverse and representative of the intended population to prevent algorithmic or clinical bias. Proposals must include strategies for identifying and mitigating potential bias in data sources.

1.4.5.4.5.6 Data Access and Licensing: Applicants must demonstrate that all datasets are legally obtained and appropriately licensed, with permission documented through data use agreements, licenses, or institutional partnerships. Discussion of required licensing must be well explained, and / or in place to ensure legal data access and utilization while adhering to data privacy laws.

1.4.5.4.6 **Data Management Plan:**

1.4.5.4.6.1 A concise data management plan should be included, outlining how data will be stored, secured, updated, shared (if applicable), and used throughout the project lifecycle.

1.4.5.4.6.2 In this regard the plan should ensure (if applicable) that data must undergo rigorous preprocessing and cleaning, including normalization, de-identification, anomaly detection, and standardization, to ensure accuracy and reliability.

1.4.5.4.6.3 Provisions for data anonymization, encryption, masking, retention, and potential reuse. Roles and responsibilities related to data handling (data controller, processor, third party service provider) must be clearly defined.

1.4.5.4.6.4 Any data transfer must comply with UAE data residency laws (Decree-Law No. 45 of 2021, the Personal Data Protection Law (PDPL)) and require prior DOH approval. Use of cloud platforms for laboratory information management, analytics, or storage must adhere to ADHICS Regulated cloud guidelines and obtain approval from DOH.

1.4.5.4.7 **Methodology for Data Analytics**: Proposals must include a clear and well-structured description of the methodology used for analyzing the data supporting the Bioconvergence innovation. This section should outline the analytical techniques, tools, and models applied whether statistical, computational, or AI-based and explain how they contribute to deriving insights, validating hypotheses, or informing clinical or technological decisions. The methodology must be appropriate for the type and quality of data used and aligned with the project's objectives. Specifically, applicants should:

1.4.5.4.7.1 Describe the data processing pipeline, including cleaning, transformation, feature selection, and normalization steps.

1.4.5.4.7.2 Specify the analytical methods (e.g., machine learning algorithms, predictive modeling, statistical tests, real-world evidence synthesis, etc.).

1.4.5.4.7.3 Describe if there will be utilization for blockchain if any for data traceability and security.

1.4.5.4.7.4 Justify the choice of methods in relation to the data type, intended use, and expected outputs.

1.4.5.4.7.5 Outline the validation approach, including performance metrics, cross-validation, or benchmarking strategies. For AI models: AI models will need validation through cross-validation techniques, implement explainable AI for transparency, and use ensemble methods to enhance predictive accuracy (see the subsequent section for further details).

1.4.5.4.7.6 Address how the methodology ensures reproducibility, transparency, and minimizes analytical bias.

1.4.5.4.7.7 Utilize predictive analytics and statistical modelling to assess the potential impact of Bioconvergence in healthcare.

1.4.5.4.7.8 All sensitive data must be encrypted at rest and in transit using UAE approved cryptographic standards.

1.4.5.4.7.9 System must enforce strong access control policies, including Role-based Access control (RBAC), Multi-Factor Authentication (MFA), and Privileged Access Management (PAM)

1.4.5.4.7.10 Security event logs must be retained for a minimum of 12 months and be monitored by a central security operation center (SOC)

1.4.5.4.8 **AI Utilization in Data Analytics:**

1.4.5.4.8.1 As AI is a foundational part of Bioconvergence research, the Proposals should describe AI-driven components. This is required for regulatory approvals before their full deployment. The owners of the proposed solution need to be aware of the obligation to clearly outline the methodologies used to develop, train, validate, and deploy artificial intelligence models.

1.4.5.4.8.2 The choice of AI techniques should be justified based on the nature of the data (e.g., imaging, omics, clinical text), the desired outcome (e.g., prediction, classification, treatment recommendation), and the complexity of the healthcare challenge being addressed. This is in line with regulatory classification for the proposed solution.

1.4.5.4.8.3 Applicants, when submitting their innovative solutions for regulatory approvals, are expected to comply with regulatory requirements for AI use as early as possible at the time of building the proposal considering the following:

1.4.5.4.8.3.1 Define the AI architecture to be employed such as deep learning for multi-modal or high-dimensional datasets, reinforcement learning for dynamic treatment recommendations, or federated learning for secure, decentralized data training.

1.4.5.4.8.3.2 Describe the analytical pipeline, including preprocessing, feature engineering, dimensionality reduction (e.g., PCA, t-SNE), and techniques for model interpretability and explainability.

1.4.5.4.8.3.3 Apply appropriate validation strategies (e.g., cross-validation, external testing, or prospective evaluation) and specify performance metrics relevant to the clinical context.

1.4.5.4.8.3.4 Demonstrate how AI models will support data-driven, evidence-based decision-making, and how outputs will be integrated into clinical or operational pathways.

1.4.5.4.8.3.5 Ensure transparency, traceability, and reproducibility of AI models, in line with emerging best practices and ethical AI principles.

1.4.5.4.8.4 Proposals that incorporate advanced machine learning—such as network-based learning to uncover disease mechanisms or multi-omics integration for biomarker discovery—are encouraged, provided methodological rigor is demonstrated.

1.4.5.4.8.5 Proposals that do not clearly define or justify their data analytics methodology may be considered less robust during evaluation.

1.4.5.4.8.6 DoH will work as needed to issue and maintain a holistic set of regulatory tools specific to AI use whether in early molecular research or as part of medical products / solutions. All Bioconvergence researchers and innovators should refer to these guidelines and regulatory requirements to comply with as applicable.

1.4.5.4.9 Omics that will be utilized in the R&D stage:

Omics that will be utilized have to be identified, along with the purpose behind their utilization, along with the expertise / subject matter experts / researchers that would be hired. The below key areas are not exhaustive, however provided as examples:

- **Genomics**: Studying DNA sequences to personalize treatments and enhance disease prevention.
- **Proteomics**: Analyzing protein expressions to discover biomarkers for drug development.
- **Metabolomics**: Understanding metabolic processes to create precision medicine solutions.
- **Transcriptomics**: Investigating RNA transcription to detect early disease markers and assess treatment responses.

1.4.5.4.10 **Clinical trials**

1.4.5.4.10.1 Clinical Trials may be required at later stages of the innovation's lifecycle. In early-stage research and development, applicants must justify the need for initiating clinical trials; otherwise, such trials may be deferred until a standardized prototype is available. At that point, trials will assess the safety and efficacy of the proposed solution in addressing the identified health need or problem.

1.4.5.4.10.2 Applicants are required to provide preliminary plans for both preclinical and clinical testing. At the time of transitioning from the Research and Development stage to Early Deployment stage full detailed clinical trial applications should be submitted as applicable.

1.4.5.4.11 **Project Team:** At the time of proposal submission, the project team should be sufficiently developed and structured to support the successful execution of Bioconvergence innovation. The proposal must clearly identify the team members who will be responsible for the development, testing, and potential deployment of the solution. The team is strongly encouraged to establish active linkages with both local and international academic institutions, innovation hubs, and expert mentors to strengthen capacity, foster collaboration, and enable global benchmarking. While team composition may evolve over time, the following key roles must be addressed (at a minimum):

1.4.5.4.11.1 **Team Lead:** Responsible for overall project direction, coordination, and delivery.

1.4.5.4.11.2 **Subject Matter Experts:** Scientists and researchers with expertise in relevant domains (e.g., biotechnology, engineering, AI, nanotechnology).

1.4.5.4.11.3 Core Technical Team: Individuals responsible for day-to-day development, prototyping, and technical problem-solving.

1.4.5.4.11.4 **Regulatory Affairs Expert / Consultant:** Ensures compliance with local and international regulatory standards, and alignment with applicable policies.

1.4.5.4.11.5 Clinicians & Clinical Researchers: Provide domain-specific medical input and contribute to the design and validation of clinical components.

1.4.5.4.11.6 **Data Scientists & AI Specialists: Design and develop algorithms, manage data** processing, and conduct advanced analytics.

1.4.5.4.11.7 **Ethics & Legal Advisors:** Safeguard compliance with ethical principles, patient rights, data privacy, and intellectual property laws.

1.4.5.4.12 **Research Facilities and Infrastructure:** Applicants must clearly identify the research facilities where the proposed Bioconvergence innovation activities including development, prototyping, and testing will take place. The following elements must be addressed in this section:

1.4.5.4.12.1 **Facility Description:** Provide the name, location, and type of facility (e.g., academic lab, private R&D center, startup incubator).

1.4.5.4.12.2 **Access and Agreements**: Indicate whether formal agreements are in place for facility use. If not, describe the plan for securing access, along with a justification of feasibility.

1.4.5.4.12.3 **Justification of Suitability**: Explain why the chosen facility is appropriate for the nature and scope of the project.

1.4.5.4.12.4 **Infrastructure Details**: Outline the availability and adequacy of infrastructure including specialized instrumentation, machinery, cleanrooms, data centers, wet/dry labs, or any other required technical setups.

1.4.5.4.12.5 Facilities involved must implement physical security (e.g. access controls, video surveillance), and environmental monitoring (temperature, humidity, microbiology) wherever required.

1.4.5.4.12.6 Compliance with relevant certifications or standards met by the facility (e.g., ISO, GMP, biosafety levels) that are necessary for the proposed work.

1.4.5.4.13 **Other Resources:** This section should provide sufficient clarity for reviewers to assess whether the proposed resources are adequate, realistic, and aligned with the project's scale and objectives. Applicants must provide a summary of all additional resources required to carry out the project, including the following:

1.4.5.4.13.1 **Human Resources:** Detail the workforce needs, including required skills, roles, and whether the team will be newly recruited, contracted, or drawn from existing staff.

1.4.5.4.13.2 Capital and Budget: Present a preliminary budget in tabular format, outlining key cost categories such as personnel, equipment, materials, subcontracted services, and contingency.

1.4.5.4.13.3 Justification and Assumptions: Briefly explain how the resource estimates were calculated and justified, including any market benchmarks, historical data, or vendor quotations.

1.4.5.4.13.4 Funding needs: Indicate whether adequate funding is already secured, and if so, identify the sources (e.g., internal capital, investors, public grants):

1.4.5.4.13.4.1 If funding is not yet secured, explain the applicant's funding strategy and whether DoH approval of the proposal is expected to support upcoming investment discussions or pitches.

1.4.5.4.13.4.2 Applicants may also indicate whether support from DoH is needed to identify or access potential funding opportunities, partnerships, or grant mechanisms.

1.4.6 Proposal Review and approval:

1.4.6.1 Panel Review and Early Scientific Advice:

1.4.6.1.1 DoH values early-stage funding for impactful Bioconvergence innovation projects. In collaboration with other government bodies.

1.4.6.1.2 DoH will establish an Ad-hoc Expert Panel to provide advisory services and secure incentives to support the development of high-quality, effective, and safe Bioconvergence solutions for patients. Support will correspond to technological and regulatory readiness levels, from early-stage research (TRL 1-3) to advanced clinical application and commercialization (TRL 7-9). This classification helps determine funding, regulatory oversight, and market readiness. Part **9.3** of this document details the review and support process.

1.4.6.1.3 For early-stage innovation research proposals, the Panel may offer one or more of the following:

1.4.6.1.3.1 Data licensing for approved use of existing datasets under DoH or partner governance.

1.4.6.1.3.2 Proposal approval to advance to the next stage: Research and Development leading to discovery or prototype.

1.4.6.1.3.3 IRB-Ethical approval if applicable.

1.4.6.2 Post Proposal Approval:

1.4.6.2.1 After the proposal is approved, the developer or applicant team may commence fundraising and initiate research at facilities and laboratories according to the plan outlined in the proposal.

1.4.6.2.2 Any change in the proposal must be reported to DoH. DoH will determine whether the change is approved or if the applicants need to resubmit the proposal.

2. Stage 2: Research & Development (R&D)

The Research and Development (R&D) phase represents a foundational stage in the Bioconvergence innovation lifecycle. It is the stage that preceded the testing of the solution on humans. Upon successful completion of this stage and positive evaluation outcomes, the innovation may be approved to move forward to full deployment (upscaling) and subsequently to commercialization, provided it meets all regulatory, technical, and ethical requirements.

2.1 Goals of the BC Policy for the "R&D" Stage:

The primary goal of this policy at this stage is to ensure responsible, ethical, and scientifically sound research that leads to successful outcomes as outlined above. In this regard, DoH aims to promote

a structured and collaborative R&D environment that fosters innovation while maintaining public trust, patient safety, and regulatory compliance. Main goals are outlined below:

2.1.1 Encourage interdisciplinary collaboration across biology, engineering, AI, and digital technologies.

2.1.2 Ensure ethical conduct in research, particularly in relation to biosafety, and data protection.

2.1.3 Promote transparency and reproducibility in research methodologies and results.

2.1.4 Support early integration of regulatory considerations to de-risk development and streamline future approvals.

2.1.5 Enable access to shared research infrastructure, data sets, and expert networks.

2.1.6 Align R&D activities with national health priorities and global scientific advancements.

2.1.7 Facilitate timely translation of promising concepts into scalable, clinically relevant solutions. This policy framework recognizes that innovation must be balanced with accountability and foresight to deliver real value to patients and the healthcare system.

2.2 **Stage 2 (R&D) Success Criteria:**

A successful outcome from the research and development stage of a Bioconvergence innovation may be demonstrated through one or more of the following according to the problem statement and the nature of the solution the developers proposed:

2.2.1 Development of a validated proof of concept that demonstrates the feasibility, functionality, and potential impact of the proposed solution in a controlled environment.

2.2.2 Completion of robust preclinical research that yields reliable and reproducible results, establishing a strong foundation for future clinical trials or product development.

2.2.3 Generation of novel scientific insights or discoveries that significantly advance understanding in areas such as disease mechanisms, diagnostics, therapeutic approaches, or human-machine integration.

2.2.4 Creation of enabling technologies or platforms (e.g., AI models, biosensors, engineered tissues) that can be scaled or adapted for broader healthcare applications.

2.2.5 Other outcomes that are important for the sustainability of innovation:

2.2.5.1 Establishment of intellectual property (IP) or technology disclosures that protect innovation and support future commercialization pathways.

2.2.5.2 Formation of strategic partnerships with academic institutions, research centers, or industry, helping to accelerate development and ensure real-world applicability.

2.3 **Early Regulatory Input and alignment:**

2.3.1 **Developers** are strongly encouraged to seek early regulatory input on the design and execution of their preclinical development plans. Engaging with regulatory authorities at this stage helps ensure that the methodology, data quality, and intended outcomes of the innovation are aligned with the standards required for future evaluation and approval. This proactive approach increases the likelihood that the solution or discovery will be considered acceptable and eligible for regulatory clearance during commercialization.

2.3.2 To facilitate this process, DoH offers pathways for early scientific advice and regulatory consultation through its Expert Panel and associated advisory mechanisms. These

forums provide developers with tailored guidance to optimize regulatory alignment, mitigate risks, and support evidence generation strategies from the earliest stages of development.

2.3.3 Ethical and environmental impact assessments should be conducted. These assessments should be reviewed and approved by DOH to ensure conformity with regulatory requirements.

2.4 **Preclinical Development for safety testing** is a critical component of Research and Development phase, and necessary to transit to Early Deployment phase where the solution including its components will be tested in humans and real-world settings.

2.4.1 This part is expected to involve thorough safety and efficacy testing of Bioconvergence solutions before they are introduced to human subjects.

2.4.2 In this stage it is empirical to ensure rigorous compliance with established laboratory practices and ethical standards ensures the robustness and credibility of the research outcomes.

2.4.3 Developers should conduct rigorous preclinical studies, including in-vitro, in-vivo, and organ-on-chip models, to establish safety, efficacy, pharmacokinetics, and pharmacodynamics.

2.4.4 If applicable, integration of AI-based predictive toxicity / harm / safety models is highly encouraged to enhance precision in risk assessment.

2.4.5 Comprehensive documentation should be maintained throughout the preclinical phase, including experimental protocols, data logs, and risk mitigation strategies.

3. Stage 3: Early Deployment: (Prototype Clinical Feasibility)

3.1 The Early Deployment stage marks a pivotal phase in the Bioconvergence innovation lifecycle, where the developed prototype or solution transitions from controlled research environments into real-world, human-centered evaluation.

3.1.1 This stage typically involves pilot-scale clinical trials, limited deployment in healthcare settings, or performance studies to generate real-world evidence. The primary goal is to validate the safety, efficacy, usability, and scalability of innovation in practical settings before full-scale deployment or commercialization.

3.1.2 This stage serves as both a proof of readiness and a risk mitigation step, ensuring that only well-validated and impactful Bioconvergence innovations advance to widespread adoption. Accordingly, a risk-based approach in this stage is required to carefully evaluate safety and efficacy while safeguarding human subjects through comprehensive ethical oversight.

3.1.3 Scaling production from lab to industry remains complex and resource-intensive, requiring targeted support for early-stage innovation [3]. Scaling up plans should be clear at this stage at least the overall process need to be discussed, to ensure early deployment ends up with a successful transfer to the later stages up to commercialization [3]

3.2 Goal **of the Policy for Early Deployment Stage**:

3.2.1 Ensure early safety and feasibility are assessed under regulatory supervision and oversight. This supervision can take the form of a regulatory sandbox.

3.2.2 Foster clinical readiness through structured and phased evaluation.

3.2.3 The Bioconvergence Research outcome presented through an internationally acceptable file for a fully standardized Refined Prototype ready for regulatory approval.

3.3 Elements for "Early Deployment" stage from regulatory alignment point of view:

3.3.1 **Clinical Trials Framework**: clinical trial pathways for bioconvergent technologies will be developed, including hybrid or adaptive trials.

3.3.2 **Patient Safety and Vigilance**: Mandate real-time monitoring systems and adverse event reporting tailored to complex, integrated technologies.

3.3.3 **Interoperability & Standards**: Set standards for integration with existing healthcare systems and technologies.

3.3.4 **Regulatory Feedback Loop**: ensure continuous feedback through utilization of regulatory sandboxes or early advice mechanisms for developers.

3.4 **Successful outcome of stage 3 "Early Deployment" is characterized by:**

3.4.1 Refinement of the product or solution based on real-world feedback, addressing any gaps identified during testing.

3.4.2 Reproducibility: Innovations must undergo rigorous testing in controlled environments to confirm that results are consistent across repeated trials and experiments. This is to ensure that Bioconvergence solutions are replicable, and the results are obtainable based on the original setting.

3.4.3 Generalizability: Bioconvergence technologies shall be scalable and adaptable to broader intended patient populations, ensuring that their benefits are not limited to a narrow subset of cases.

3.4.4 Completion of clinical evaluations or field testing demonstrating positive results in terms of patient safety, intended performance, and clinical benefit.

3.4.5 Evidence of operational feasibility, including integration with existing healthcare workflows, systems, or infrastructure.

3.4.6 Regulatory and ethical clearance to proceed to broader deployment or market introduction.

3.4.7 Early partnerships or procurement interest from stakeholders, signaling market readiness and societal value.

3.5 **Proposal submission for initiation of the Early Deployment Phase:**

Upon completion of the Research and Development phase successfully, developers wishing to transit into Early Deployment Stage are required to submit a proposal for advancing the Outcome Prototype/ Medical Product/ Solution to the Early Deployment stage.

3.5.1 **The** proposal's requirements will be discussed with the concerned Sector at DoH to tailor it according to the nature of the Product and its early deployment plan.

3.5.2 The Proposal for kicking off the "**Early Deployment" phase** should include:

3.5.2.1 Comprehensive report detailing the outcomes achieved from the R&D phase.

3.5.2.2 The full description of the finalized and standardized prototype or solution.

3.5.2.3 All Evidence generated at the R&D stage along from literature to prove the technical feasibility, safety, and functional validation of the proposed solution prototype.

3.5.2.4 Clinical Trials Plan along with brief on its protocols and evidence generation methodology, including statics. Clinical trials conducted during this phase will generate the evidence required to assess the safety, efficacy, usability, and real-world applicability of the solution. For more details on this section developers can refer to the subsequent relevant sections below.

3.6 **"Early Deployment phase" proposal evaluation**: DoH, in collaboration with its expert panel and strategic partners, will assess the submission to ensure that the prototype:

3.6.1 It is fully standardized and reproducible.

3.6.2 Meets relevant regulatory, safety and quality standards.

3.6.3 It has undergone thorough preclinical validation.

3.6.4 Demonstrates functional integrity and readiness for initial human testing.

3.7 **Early Deployment proposal approval**: Only solutions that fulfil the above criteria will be considered eligible to proceed to the Early Deployment phase, where limited-scale clinical testing or pilot implementation may begin under controlled conditions and clinical trial frameworks apply. This process ensures a responsible and evidence-based progression of Bioconvergence innovations toward real-world application.

3.8 Regulatory alignment in Early Deployment stage

3.8.1 Engagement with regulatory bodies:

3.8.1.1 Early and proactive engagement with relevant regulatory authorities is essential prior to initiating the clinical trial stage—particularly when the prototype or any of its components are novel, experimental, or fall under emerging technology classifications locally.

3.8.1.2 The goal from such engagement ensures that the proposed solution complies with applicable national and international regulatory frameworks, including those related to safety, ethics, and quality standards.

3.8.1.3 Early engagement can help identify potential regulatory hurdles, streamline approval processes, and increase the likelihood of successful progression through clinical and commercial stages.

3.8.2 Potential Regulatory pathways for the intended Bioconvergence solutions / Medical product need to be explored internationally and locally as possible to be identified and aligned with: Developers should explore and reference established frameworks issued by Reference Regulatory Authorities and or Reference Harmonization Bodies as applicable (such as but not limited to the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), and the International Council for Harmonization (ICH) along with the requirements issued by DOH and Emirates Drug Establishment (EDE)).

3.8.3 For Regulatory alignment process the following need to be considered:

3.8.3.1 Clarifying the regulatory classification of the innovation (e.g., medical device, combination product, advanced therapy, AI-based diagnostic) as per international rules

published by reference regulatory authorities and/or reference harmonization / standardization bodies as applicable.

3.8.3.2 Understanding the pathway for clinical trial authorization or investigational use approval locally and internationally if applicable.

3.8.3.3 Ensuring adherence to ethical guidelines, such as informed consent, data protection, and risk-benefit assessment.

3.8.3.4 Aligning with legal and policy requirements, including good clinical practice (GCP), Good manufacturing Practice GMP, and other good Practices GXP as applicable. Additionally human subject research protections, and intellectual property considerations need to be fully complied with.

3.9 **Clinical Trial Framework:** To transition into the Early Deployment stage, the use of the developed prototype must only occur within a clinical trial framework, adhering to all applicable regulations and ethical standards governing human research. This includes the submission of a complete clinical trial protocol for review, followed by evaluation and approval by DoH and relevant oversight bodies (e.g., Institutional Review Boards or Ethics committees).

3.9.1 **Clinical Trial Phases** for Bioconvergence: Bioconvergence solutions that are standardized and classified as medical products should undergo distinct phases to ensure safety and efficacy before authorization by the Relevant Regulatory Authority for its upscaling / commercialization:

3.9.1.1 **First-in-Human (FIH):** DoH requires a detailed application for a carefully designed for First -in Human trial for very limited number of patients to be conducted in sequential manner if the substantial risks are encountered.

3.9.1.2 **Phase I**: Conducted with a small group of healthy volunteers to assess safety, dosage, and side effects.

3.9.1.3 **Phase II**: Involves a larger group of patients to evaluate efficacy and further assess safety. In some Bioconvergence solutions, the relevant regulatory authority may approve the outcome under conditional approval framework (e.g. solutions or medical products indicated for orphan or rare diseases)

3.9.1.4 **Phase III**: Large-scale trials to confirm effectiveness, monitor side effects, and compare with standard treatments.

3.9.1.5 **Phase IV**: Post-marketing studies to collect additional information regarding long-term use and effectiveness.

3.9.2 Compliance with DoH Standards:

3.9.2.1 All clinical trials must comply with DoH Standard on Human Subject Research. This includes adherence to ethical guidelines covering informed consent, risk-benefit analysis, scientific validity, and comprehensive post-market monitoring frameworks.

3.9.2.2 Compliance with Good Clinical Practices (GCP) is required, including patient stratification using AI-powered analytics and digital monitoring of adverse effects.

3.9.2.3 Detailed clinical trial protocols and outcomes should be reported to the DOH, ensuring transparency and accountability throughout the research process.

3.9.2.4 DoH will evaluate the application based on its alignment with national regulatory standards, best international practices, and its potential contribution to healthcare innovation in Abu Dhabi.

3.9.2.5 Clinical Trials applications should undergo risk-based evaluation, integrating Real-World Data (RWD) and Real-World Evidence (RWE) to support safety, efficacy, and patient-centered outcomes.

3.9.2.6 Comprehensive post-trial monitoring should be implemented to assess long-term risks, benefits, and any unforeseen adverse reactions. These monitoring reports should be submitted periodically to DoH for review, Key Features:

3.9.2.6.1 Combines in-person visits with remote monitoring, telehealth, and digital tools (e.g., wearable sensors, ePROs).

3.9.2.6.2 Using electronic consent, remote diagnostics, and home-based data collection will bring many benefits, like expanding geographic reach and patient access, especially in underserved populations. Additionally, it improves patient convenience and retention. Most importantly it enables real-world data collection and enhances diversity in clinical trial populations.

3.9.3 Use Cases:

3.9.3.1 Chronic disease management

3.9.3.2 Monitoring post-market treatments

3.9.3.3 Trials during pandemics

3.9.4 Developers should obtain DoH approval for ethical oversight, Informed Consent 2.0 and Institutional Review Board (IRB) evaluation. Detailed risk mitigation plans should be in place prior to trial initiation.

3.9.5 Trials should include human subjects that are representative of the intended use populations to ensure generalizability of results.

3.9.6 **Submission of the Clinical trial application:** the applicant (whether a proposal team, startup, or consortium) must submit a complete application for clinical trial authorization in line with DoH requirements. This submission must include:

3.9.6.1 The full trial protocol.

3.9.6.2 Clearly defined primary and secondary outcomes (including safety and efficacy endpoints).

3.9.6.3 A detailed description of the final standardized solution.

3.9.6.4 A plan for data collection, analysis, and regulatory reporting.

3.9.7 **Adaptive and Hybrid designs in Clinical Trials for Early Deployment Phase:** Both trial designs are especially relevant for Bioconvergence innovations as they align with precision, agility, and ethical responsibility, which are key principles in next-generation healthcare innovation which often:

- Involve novel mechanisms or multidimensional outcomes.
- Require flexibility to optimize based on emerging data.
- Benefit from technology-enabled data capture and patient engagement tools

3.9.7.1 **Adaptive Clinical Trials:** An adaptive clinical trial is a trial that allows pre-planned modifications to the trial design or parameters based on interim data analysis without undermining the validity or integrity of the study.

3.9.7.1.1 Key Features:

3.9.7.1.1.1 Adaptations are pre-specified in the trial protocol.

3.9.7.1.1.2 Modifications can include:

i. Changing the sample size
ii. Adjusting dosing regimens
iii. Dropping or adding treatment arms
iv. Modifying inclusion/exclusion criteria.
v. Stopping the trial early for futility or efficacy

3.9.7.1.2 **Benefits**:

i. Increases efficiency by focusing resources on the most promising treatments.
ii. Reduces patient exposure to ineffective or harmful treatments.
iii. Enables faster decision-making and potential early access to effective therapies.

3.9.7.1.3 Use Cases:

i. Oncology
ii. Rare diseases
iii. Personalized medical products/ precision medicine
iv. Complex, multi-arm trials (e.g., platform trials like Recovery for COVID-19)

3.9.7.2 Hybrid Clinical Trials: Hybrid clinical trials (sometimes called decentralized or virtual trials) combine traditional on-site trial elements with digital or remote technologies to allow more flexibility in patient participation and data collection.

4. Stage 4: Upscaling, Granting Regulatory Approval and Commercialization

4.1 **It** is important to note that despite the stage of Granting Regulatory Approval (Marketing Authorization) for (large scale deployment) is only possible based on a successful phase 1,2 & 3 completion with proven favorable risk benefit ratio for the innovated medical Product / solution. However, the submissions for this approval ideally start after a successful R&D and at the beginning of clinical trials phase 1, 2 & 3.

In some cases, phase 2 clinical trials are sufficient to get conditional marketing authorization, that is granted on conditional basis mainly completion of phase 3 clinical studies.

4.2 **Goal of the Policy for Granting Regulatory Approval Stage:** Ensure safety, effectiveness, and clarity in regulatory pathways.

4.3 Elements need to be considered for regulatory applications and approval:

4.3.1 Right Archetype Classification for the targeted medical Product/ Solution.

4.3.2 Risk Classification: Establish risk categories and required documentation for each class.

4.3.3 Evidence Requirements: Set expectations for clinical, technical, and cybersecurity evidence.

4.3.4 Cross-border Harmonization: Align with international standards where possible (e.g., IMDRF, ICH, ISO).

4.3.5 Multicomponent Solutions:

4.3.5.1 If the Solution includes more than one standalone usable component, under certain archetype, then each component should be approved separately according to its

regulatory archetype classification. Then the combination should be subject to additional approvals to be deployed on a large scale.

4.3.5.2 If the Solution is composed of multiple components but many are not usable on their own, then the combined solution should be classified according to its main use and mode of action.

4.3.5.3 Tailored Regulatory Pathways: work with partner regulatory bodies to define clear approval tracks for various types of bioconvergent products (e.g., AI-driven diagnostics, biohybrid implants).

4.4 Regulatory Sandbox:

Sandbox framework is one of the adaptive approaches, to evaluate Bioconvergence solutions. The Regulatory Sandbox provides a controlled environment for testing innovative Bioconvergence solutions under real-world conditions. It allows developers to demonstrate the feasibility and safety of their solutions while adhering to regulatory standards. This approach encourages innovation while maintaining public safety and compliance.

4.4.1 DoH will work with the concerned regulatory bodies on establishing adaptive regulatory frameworks to be available for emerging therapies, with periodic re-evaluation to ensure continued compliance and safety.

4.4.2 The Sandbox will provide developers with guidance on regulatory expectations.

4.4.3 AI-driven regulatory decision-support tools will be integrated to facilitate real-time risk assessments and continuous policy refinements based on evolving scientific knowledge.

4.4.4 A centralized digital regulatory platform will be developed for real-time tracking, compliance monitoring, and digital licensing to streamline the approval process.

4.4.5 An inter-agency Regulatory Bioethics Committee will oversee adherence to bioethical standards, ensuring that innovations respect patient rights and public safety.

4.5 Good Practices (GxP), Organizational Excellence, and Data Integrity:

Implementing best practices in good laboratory, clinical, manufacturing, and distribution processes is fundamental to maintaining quality and integrity. This section outlines the standards that organizations should follow to ensure compliance and ethical data handling.

4.5.1 Compliance with GLP, GCP, GMP, and GDP is mandatory, with regular training and certification programs to maintain competency.

4.5.2 Organizations should implement Standard Operating Procedures (SOPs) and utilize AI-based compliance tracking to minimize human errors.

4.5.3 Data integrity frameworks, including blockchain and federated learning, should be adopted to maintain ethical data handling and cybersecurity.

4.5.4 AI-driven fraud detection systems will be implemented to prevent data manipulation and non-compliance, ensuring the authenticity of clinical and manufacturing data.

4.5.5 Good Machine Learning Principles (GML) [20], need to be strictly followed and demonstrated. The U.S. Food and Drug Administration (FDA), Health Canada, and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) have jointly identified 10 guiding principles that can inform the development of Good Machine Learning Practice (GMLP). These guiding principles will help promote safe,

effective, and high-quality medical devices that use artificial intelligence and machine learning (AI/ML) **(see figure below)**

10 principles of Good machine Learning (IDMRF, 2025) (25)	
1. Intended use and multi-disciplinary expertise	2. Software engineering and security best practices
3. Representative clinical evaluation datasets	4. Independence of training and test datasets
5. Fit-for-purpose reference standards	6. Tailored model choice and design
7. Human-AI interaction assessment	8. Clinically relevant performance testing
9. Clear and essential user information	10. Ongoing performance monitoring and retraining risk management

4.6 **International Regulatory Compliance:**

To facilitate global adoption and commercialization, Bioconvergence solutions should align with international regulatory standards. This section provides guidance on achieving compliance with major global health authorities and fostering international cooperation.

4.6.1 Developers should align their solutions with global regulatory bodies (FDA, EMA, WHO, ICH, ISO, OECD) to facilitate international acceptance and market entry.

4.6.2 Cross-border regulatory harmonization and Mutual Recognition Agreements (MRAs) will be pursued to streamline international trade and approval processes.

4.6.3 AI-driven compliance monitoring will be adopted to ensure adherence to evolving international regulations and standards.

4.7 Audits & Quality Assurance:

4.7.1 Maintaining high standards of quality and compliance throughout the lifecycle of Bioconvergence solutions is essential. Periodic audits will be conducted by DoH team to ensure compliance with regulatory requirements under the oversight of DoH.

4.7.2 All developers should comply with DOH licensing requirements, health regulations, ethical guidelines, and data privacy standards prior to and during market entry.

4.7.3 DOH will conduct periodic regulatory assessments and establish a Real-Time Compliance Dashboard to monitor adherence to regulatory requirements.

4.7.4 Non-compliance may result in penalties, suspension, or revocation of approvals, with clear escalation protocols and remediation plans in place.

5. Stage 5: Lifecycle Management, Post-Market Surveillance& Innovation Feedback:

Surveillance& Innovation Feedback) would be:

5.1.1 to sustain innovation while protecting public health and fostering trust.

5.1.2 Support continuous improvement and safe iteration.

5.1.3 Post-Market Monitoring: Define real-world evidence and performance monitoring requirements.

5.1.4 Continuous Learning Systems: Encourage AI models and systems to be regularly updated with new data, with validation protocols.

5.1.5 Health Equity & Access: Promote fair access and avoid algorithmic or systemic biases in deployment.

5.1.6 Sustainability & Environmental Impact: Address waste, resource use, and eco-safety of high-tech solutions.

5.1.7 Recall & Incident Reporting: Set mechanisms for recalling or malfunctioning or unsafe products.

5.1.8 Safety Profile Updating.

5.2 Post market surveillance and safety monitoring:

In this phase, ongoing post-market surveillance is mandatory for developers / marketing authorization holders, should be implemented to monitor the real-world effectiveness and safety of Bioconvergence innovations, allowing for continuous refinement and risk mitigation.

5.3 Main considerations for this stage are:

5.3.1 Version Control & Re-certification: Especially for adaptive systems (e.g., machine learning models), mandate periodic review and re-certification.

5.3.2 Legacy System Integration: Ensure continued support and safety for earlier versions in clinical settings.

5.3.3 Stakeholder Engagement: Require user feedback mechanisms (clinicians, patients, regulators).

5.3.4 Retirement or Decommissioning: Set standards for end-of-life management and transition plans.