Department of Science, Technology, Engineering and
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UCL

Future Standards for Bio-digital Convergence

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List of Abbreviations

ahG7	IEC System Committee BDC's Ad-hoc Working Group on Ethical and societal considerations
BDC	Biodigital Convergence
BNCT	Bio-, Nano-, and Converging Technologies (Also MANBRIC)
BSI	British Standard Institution
DSIT	Department for Science, Innovation and Technology
IEC	International Electrotechnical Commission
IEC SEG 12	IEC Standardization Exploratory Group on Bio-digital Convergence
IEC/ISO JSyC BDC	IEC/ISO Joint System Committee on Bio-Digital Convergence
IEC/ISO JTC 3	IEC/ISO Joint Technical Committee on Quantum technologies
ISO	International Organization for Standardization
ISO/IEC JTC 1	IEC/ISO Joint Technical Committee on Information technologies
MANBRIC	Bio-, Nano-, and Converging Technologies (Also BNCT)
NBIC	Nano-Bio-Info-Cogno Technology
MHRA	Medicines and Healthcare products Regulatory Agency
PAGIT	Proportionate and Adaptive Governance of Innovative Technologies
SC	Subcommittees
SDOs	Standards development organizations
SyC	Systems Committee
TC	Technical Committees
2023 UK Vision	National Vision for Engineering Biology
WG2	IEC SEG 12's Working Group 2: Reverse Engineering of Living Systems
WG3	IEC SEG 12's Working group 3: Life Systems and Bioengineering
WG4	IEC SEG 12's Working group 4: Human Augmentation Technologies
WG5	IEC SEG 12's Working group 5: Agricultural Bioengineering
WG6	IEC SEG 12's Working group 6: Environmental Bioengineering
WG7	IEC SEG12's Working Group 7: Social, risk and ethical aspect related to BDC
WHO	World Health Organization
WTO	World Trade Organization

Executive Summary

Bio-digital convergence ("BDC") as a field lies at the intersection of biological and digital technology spheres, creating transformative opportunities across various sectors, including healthcare, agriculture, and environmental protection. However, challenges and risks will be exacerbated or emerge as they continue to grow and evolve. This report, conducted in partnership between the British Standards Institute ("BSI") and post-graduate research students and University College London ("UCL") explores the role of standards within this ecosystem, identifying specific UK standardization opportunities and challenges within the emerging field of BDC.

Methodology
The project utilized a mixed-methods approach to facilitate a comprehensive exploration of the BDC landscape, with the research being conducted in two main stages. The first stage involved a desk-based literature review to map the BDC landscape and identify emerging trends and critical technologies most relevant to the UK and BSI. The second stage leveraged primary data collection through committee observations, semi-structured interviews, and an expert focus group to interrogate the specific role of standards into the broader ecosystem. This approach supported a thorough understanding of existing standardization efforts and identifying future opportunities. Given the transformative impact BDC technologies have in the world—and the intrinsic ways society also shapes the emergence of BDC—the research introduced a "socio-environmental impact lens" to evaluate and engage with the landscape. In this way, the specific ways standards support ethical and sustainable innovation in the BDC sphere came to the forefront.

Key Findings

- **Understanding the Wider BDC Landscape:** The report establishes the multifaceted and complex ecosystem within which BDC exists, emphasizing its interdisciplinary nature and the need for a nuanced understanding of the interactions between biological and digital systems. Standards are just one element in an expansive network.
- **BDC Standardization Landscape:** The BDC standardization landscape is rapidly evolving, with key international bodies such as the International Electrotechnical Commission ("IEC") and the International Organization for

Standardization (“ISO”) driving efforts to harmonize practices across disciplines.

- **Stakeholder Identification:** A diverse range of stakeholders involved in BDC were identified who play a critical role in shaping the development and governance of BDC technologies through standardization processes. These include government bodies, academia, industry players, and the public.
- **Opportunities for Standardization:** The report reveals multiple opportunities where standards can play a pivotal role, including building public trust through transparency and accountability, reducing disparities in access to BDC technologies, and enhancing productivity and innovation through best practice standards.
- **Ethical and Social Implications:** BDC standards must be developed with explicit regard to their ethical and social impacts. The report analyses frameworks like Proportionate and Adaptive Governance of Innovative Technologies (PAGIT), which can incorporate principles of responsible innovation into BDC standardization.
- **UK Opportunities and Strengths:** The report highlights what and where the UKs strengths in BDC lie and how these maps to its national goals. Its rich history in synthetic biology and genomics position it well to lead in BDC standardization efforts. Through bodies like BSI, the UK can play a crucial role in standardization, ensuring that national interests and knowledge align with global standards.

Recommendations

- BSI could take a system approach to organize a national BDC committee.
- BSI could adopt the horizontal and vertical structure as the basis of its system committee.
- BSI could enhance consideration of social impact into the development of standards—both in its structures and the methods it uses.
- Consider introducing case study approaches.
- Continue to incorporate PAGIT Frameworks.
- Explore specific methods for involving direct end users.

The report highlights the importance of standards in ensuring that BDC technologies are developed and deployed in ways that are socially responsible, ethically sound, and promote sustainable innovation.

1 Introduction

Bio-digital convergence ("BDC") represents a groundbreaking interaction between biological and digital technologies, offering transformative potential across various sectors. This rapidly evolving field blurs traditional disciplinary boundaries, creating innovative tools and applications to revolutionize healthcare, manufacturing, agriculture, and environmental protection. However, the complexities introduced by BDC also present significant challenges, particularly in standardization, ethical considerations, and technological compatibility.

In recent years, there has been growing recognition of the need for standardized approaches within BDC. International organizations such as the IEC and the International Organization for Standardization ISO have initiated global standardization efforts aimed at harmonizing practices, ensuring safety, and facilitate international collaboration (§3 and §8.3). These efforts are crucial as the convergence of biological and digital systems continues to advance, bringing the potential for both significant innovations and substantial risks.

> This project was conceived in response to these emerging needs, with the primary aim of exploring and defining the standardization opportunities and challenges within the emerging field of BDC. The BSI's interest in this project is driven by the need to understand the specific standardization challenges and opportunities within the UK context, particularly in sectors considered priorities, like healthcare and agriculture (§3 and §4.4.1), poised to benefit significantly from biodigital innovations.

To guide the reader through the comprehensive analysis presented in this report, the document is structured as follows:

The Background section provides an overview of the landscape of global standardization efforts and UK priorities that have influenced the project's focus.

The Methodology section details the approach used to investigate the research questions. It starts by defining the study's scope and limitations, followed by a comprehensive explanation of the first stage, which involved desk-based research, including a literature review, bibliometric analysis, and stakeholder mapping. The second stage, which focused on primary data collection, is then discussed, emphasizing the semi-structured interviews, expert workshop (Focus Group), and committee observation conducted to gather key insights.

In the Research Findings (Analysis) section, the insights gathered from both stages of the research are presented. This section explores the current research and technological activities within the BDC field, the evolution of terminology, stakeholder mapping, the identification of emerging areas for standardization, and the ethical and social implications of BDC technologies.

The Discussion section builds on these findings, providing a deeper analysis of the biodigital convergence landscape. It explores the conceptual boundaries of BDC, its interactions with society and the environment, and how these insights shape standardization opportunities and ethical considerations.

Following this, the Recommendations section offers actionable insights for policymakers, industry leaders, and standardization bodies, based on the research findings and discussions.

Finally, the report concludes by synthesizing the key takeaways from the study, highlighting the essential role of standardization in supporting the responsible development and deployment of biodigital technologies.

The findings from this project are intended to inform BSI's strategic planning and contribute to the broader international dialogue on BDC, ensuring that the UK plays a pivotal role in shaping the standards that will govern this transformative field.

2 Background of the Project

In the past year, there has been a significant acceleration in global and UK standardization activities related to BDC, driven by the need for robust, safe, and ethical standards in this rapidly evolving field.

2.1 Global Efforts in BDC Standardization

On the global stage, this momentum led to the establishment of the IEC SEG 12 committee in March 2023, which has now transitioned into the IEC/ISO Joint Systems Committee on Bio-Digital Convergence (IEC/ISO JSyC BDC). This global committee is tasked with overseeing systems-level standardization efforts across both IEC and ISO, including key areas such as information technology and quantum technologies, ensuring that BDC advancements are accompanied by interoperable and ethical practices. (§8.3).

2.2 UK Vision and Priorities for BDC

In February 2023, then-UK-Prime Minister Rishi Sunak established the Department for Science, Innovation, and Technology ("DSIT") to "create the most innovative economy in the world" and support the UK's rise as a "science superpower" (1). Five key technologies are at the heart of DSIT's mission: engineering biology, quantum technologies, AI, semiconductors, and future telecommunications.

The UK's 2023 National Vision for Engineering Biology ("2023 UK Vision") outlines key priorities for developing the infrastructure, standards, and regulatory frameworks to position the UK as a global leader in bioengineering. While "biodigital convergence" is not mentioned explicitly by name, its core concepts directly intersect with the technologies, applications, and sectors identified in the report—like synthetic biology and artificial intelligence-enabled gene sequencing.

The strategy highlights the integration of these areas into educational curricula to build skills and talent, the creation of innovative spaces to support startups, and the promotion of cross-sector adoption to drive innovation and ensure the swift, safe introduction of products, including those the research team have identified as BDC, to the market (1).

The UK is committed to enhancing international collaboration by forging partnerships that bolster its position on the global stage, ensuring that UK standards for BDC align with international norms to enable worldwide marketing of UK products. In this effort, the UK has actively contributed to global BDC standardization by participating in the IEC SEG 12 via the BSI's Biotechnologies Standards Committee, BTI/1, and is a P-member of the new IEC/ISO JSyC BDC. This involvement ensures that the UK's perspectives and priorities are integrated into the international standardization process, particularly in areas where the UK holds significant expertise and interest.

Furthermore, the UK plans to increase public investment in infrastructure and foster partnerships with industry and academia through public-private partnerships (PPPs) to translate fundamental research into practical applications (P6). Supported by the UK Science and Technology Framework, these strategies extend through to 2030 and aim to boost the UK's capabilities in critical technologies, including engineering biology. They emphasize leveraging government procurement, enhancing access to infrastructure, and creating favorable regulatory conditions to drive innovation.

3 Methodology

To comprehensively address the project's research questions, the team adopted a mixed methods approach, carefully chosen to account for the dynamic and emergent nature of BDC. This was done through an initial broad baseline mapping and trend exploration, to identify key standardization priorities and proactively address ethical and risk considerations. The study was structured into two distinct stages. The first stage involved desk-based research aimed at clearly framing the conceptual framework for understanding BDC. The second stage consisted of primary research, including semi-structured interviews, a focus group, and a committee observation.

3.1 Scope

This project focuses on exploring the standardization opportunities and challenges posed by BDC within the UK.

To comprehensively address the project's aim, the investigation was structured around three key areas: understanding current research and technological developments, identifying emerging standardization needs, and addressing the risks and ethical considerations associated with biodigital technologies. Specifically, the research addressed three core questions:

Table 1: Indicating the Focus Area and Research Questions

Focus Area	Research Question
Understanding current research and technological developments	Q1. What are the current research and technology activities in the field of bio-digital convergence?
Identifying emerging standardization needs	Q2. What are the emerging areas of bio-digital convergence that may be relevant for standardization?
Addressing risks and ethical considerations	Q3. How can standardization address the risks and ethical considerations associated with current and emerging bio-digital convergence technologies?

of biodigital technologies	

3.2 Limitations

This study, while comprehensive and thorough in its approach to identifying opportunities and challenges for the standardization of BDC, encountered limitations in the following areas;

The project's timeframe: Given BDC's broad scope concept, it was difficult to achieve both a sufficiently expansive and deep understanding in just four months. Yet, by identifying potential hurdles, we adapted our framework through a multi-method approach to defining the BDC landscape, whilst also offering an in-dept case study into healthcare application of BDC.

Logistical limitations: Where the initial plan was to conduct an in-person workshop, midway through our primary research, we had to switch to leading a focus group. This was primarily due to transitions towards remote working practices. Where this may have impacted participant engagement and attendance, the participant selection process assured relevance and robustness in findings.

Information bias: Relying solely on contemporaneous note taking, without the benefit of recordings, may have led to the omission of subtle nuances and key insights. However, meticulous note-taking and collective reviewing helped mitigate this. Also, the final number of workshop registrations was insufficient to form breakout, which would have enabled deeper and broader discussions on BDC. Based on participants' background we chose to concentrate our activities on the healthcare applications of BDC technologies (§4.4.1). The exclusion of other sectors further restricted the applicability of the findings to other areas.

BDC's rapid development: Finally, the rapid evolution and development of BDC technologies and its policy context could significantly impact the long-term relevance of our findings and recommendations. That being said, our findings and recommendations are based on the context of UK policy, IEC's action and BDC technology development in August 2024, and continuous monitoring of developments and changes to regulatory frameworks are also recommended to ensure that the standardization strategies remain relevant.

3.3 First Stage: Desk-based Research

3.3.1 Literature Review

A comprehensive literature review was used to provide a broad and expansive understanding of the current state of bio-digital convergence in the UK and international trends. More specifically, our goal was to set the boundaries of how we define BDC, so we may identify potential standardization gaps. In a rapidly evolving field like BDC, the most cutting-edge insights often reside in industry reports, conference proceedings, and online discussions alongside academic publications. As a result, grey literature was included alongside academic papers to capture the latest knowledge on:

- Key technologies and their potential cross-sector applications in the field of bio-digital convergence
- Areas where the UK exhibits leadership and strategic alignment with initiatives like the National Vision for Engineering Biology
- Current standards landscape, identifying potential gaps
- Emerging ethical concerns, societal impacts, and public attitudes that need to be considered through standardization.

To address these, we collected literature retrieved from two primary databases: Scopus and the Institute of Electrical and Electronics Engineers (IEEE). This generated 39 papers, which were then evenly distributed amongst the researchers for brief scanning. Once completed, only 14 of these papers were deemed informative and were therefore used in the qualitative and quantitative analyses detailed in the following sections.

3.3.2 Thematic coding

Thematic coding and visualizations were employed to conduct an initial qualitative analysis, facilitating a shared understanding of the BDC space. This was done by retrieving sections and information within the literature, particularly on the boundaries of the BDC landscape and terminology.
These highlighted sections were then connected and grouped together based on similarities of topics. This was followed by a categorization of information according to the five following themes and a table was then used to synthesize the findings (§Appendix).

Table 2: Showing the Thematic Breakdown of the Literature Review

1	BDC terminology
2	The evolutionary perception of BDC (and its impacts)
3	Platform and interfaces designed for the bio-digital system
4	Concerns and implications of BDC
5	Sectoral considerations

3.3.3 Bibliometric Analysis

Once the boundaries of BDC were established based on the initial literature review, a bibliometric analysis was undertaken to determine specific UK priorities from the wider BDC landscape.

The analysis measured the frequency of keywords related to BDC in academic publications in the UK since 2000, serving as a proxy for scientific output in the field. Findings from the research (i.e IEC frameworks, the UK Vision 2030) informed the keywords used to map these ~2300 papers.

A visualization was used to illustrate these priorities across the UK landscape (§Appendix). This exploration was instrumental in selecting appropriate research participants for the interviews and the focus group. It also helped the research team identify specific stakeholders that should be involved in any future standardization efforts by BSI.

3.4 Second Stage: Primary Data-Based Research

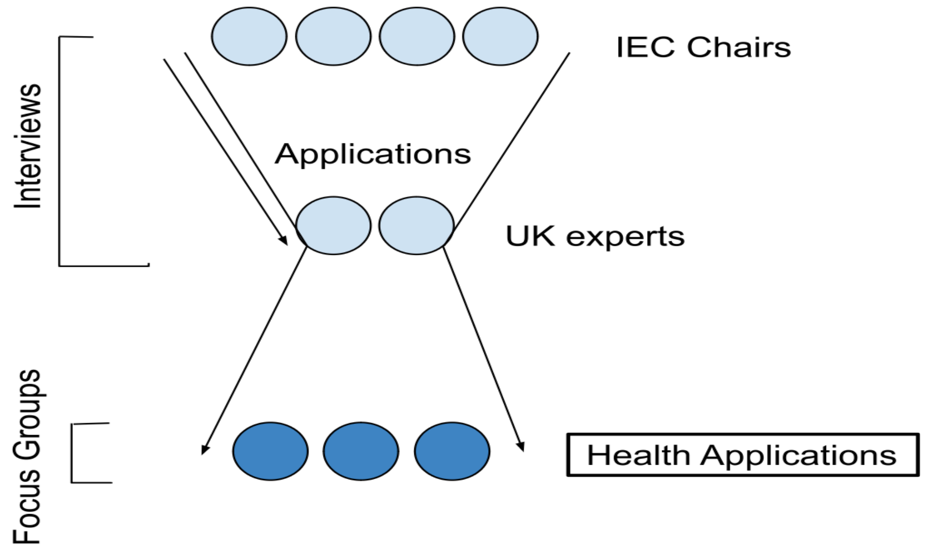
In Stage 2 of the project, we used a collaborative approach to gather primary data through qualitative methods. Key activities included conducting semi-structured interviews and a focus group. Additionally, participation in BSI's committee observations was undertaken.

3.4.1 Semi-structured interviews

The research team conducted semi-structured interviews with 6 experts. These were a key component of the primary research stage, designed to delve deeply into issues such as standardization opportunities, ethical implications, and sector-specific priorities within the field of BDC. Participant selection was intentionally diverse (§Appendix) and provided a broad range of sector-specific experiences and priorities.

The strategic approach of our interviews began with a broad perspective, engaging with IEC chairpersons to understand global standards-setting in bio-digital convergence. This set the foundation to focus specifically on the UK context, where we narrowed down to key sectors like healthcare and agriculture through targeted interviews. This methodical narrowing and expansion of focus (as illustrated in the visual below) ensured a thorough examination of both the specific and broad aspects of standardization opportunities within bio-digital convergence.

Figure 1: Mapping the Logic Behind the Primary Data Collection



3.4.2 Expert Focus Group

Through purposive and snowball sampling, we identified 22 UK-based experts spanning across BDC sectors and standardization layers, of which only three invitees confirmed attendance and all primarily stemming from the healthcare sector. This enabled us to conduct a focus group as a case study into health applications of BDC.

Having then defined the boundaries of the BDC landscape, its conceptual understanding and established a preliminary stakeholder mapping in our literature review, the goal of this group discussion was to identify critical pathways and prioritized areas for standardization relating to BDG in the UK, through the lens of social implications and ethical considerations. Through our discussions, we explored the ethical implications of data sharing, privacy concerns, and the societal impacts of emerging technologies. These insights will inform stakeholder perspectives and help develop standardization frameworks that promote responsible innovation.

3.4.3 Committee Observation

BSI invited the UCL team to observe the BSI ART/1 - Artificial Intelligence (AI) standardization committee meeting on the 19th of June 2024. This provided valuable insights into the processes, discussions, and decision-making involved in the creation of standards, particularly in the rapidly evolving area of artificial intelligence (AI), mimicking the rapidly evolving nature of BDC technologies, of which AI is one of the underpinning BDC technologies. This committee observation helped ground and contextualize the research, providing much needed insights into how committees operate and tackle standardization.

4 Analysis

4.1 Biodigital Convergence Landscape

Before delving into the specific role of standards and the opportunities for BSI, it's crucial to establish a comprehensive understanding of the broader BDC landscape. This broader understanding is essential to grasp the significance and implications of standards in BDC fully. Without this context, the role of standards might appear isolated or irrelevant. The following sections will clarify terminology, define boundaries, identify specific technologies and applications emerging from BDC, and provide an overview of the social context shaping the field. By exploring these aspects, we can build a solid foundation for appreciating the critical role standards play in shaping the future of BDC and identify opportunities for BSI to contribute to its safe and responsible development.

4.1.1 From NBIC to MANBRIC to Biodigital Convergence

The research team began the investigative process with what was assumed to be a straightforward question – what is biodigital convergence?

However, when presented to experts at the forefront of the biological and digital domains, three were initially unfamiliar with the term (P1, P6, P7). Yet, when the concept was explained, they immediately recognized its relevance to their work. One interviewee even suggested "tech bio" or "deep biotech" as more familiar alternatives (P1).

Interestingly, the term “biodigital convergence” is notably missing from the UK Vision 30, which outlines UK priorities in engineering biology driven by the intersection of digital technologies and biosciences. This absence underscores the relative novelty of the term, although the concept itself has been decades in the making. BDC represents the culmination of years of interdisciplinary collaboration and technological integration (P3), building upon and evolving from earlier concepts such as NBIC (nano-bio-info-cogno) and MANBRIC (materials-nano-bio-info-cogno) (2).

Tracing this evolutionary trajectory is crucial for understanding the vast scope and fluidity of BDC and highlighting this field's dynamic and evolving nature.

Table 3: Showing the History of BDC Conceptualization

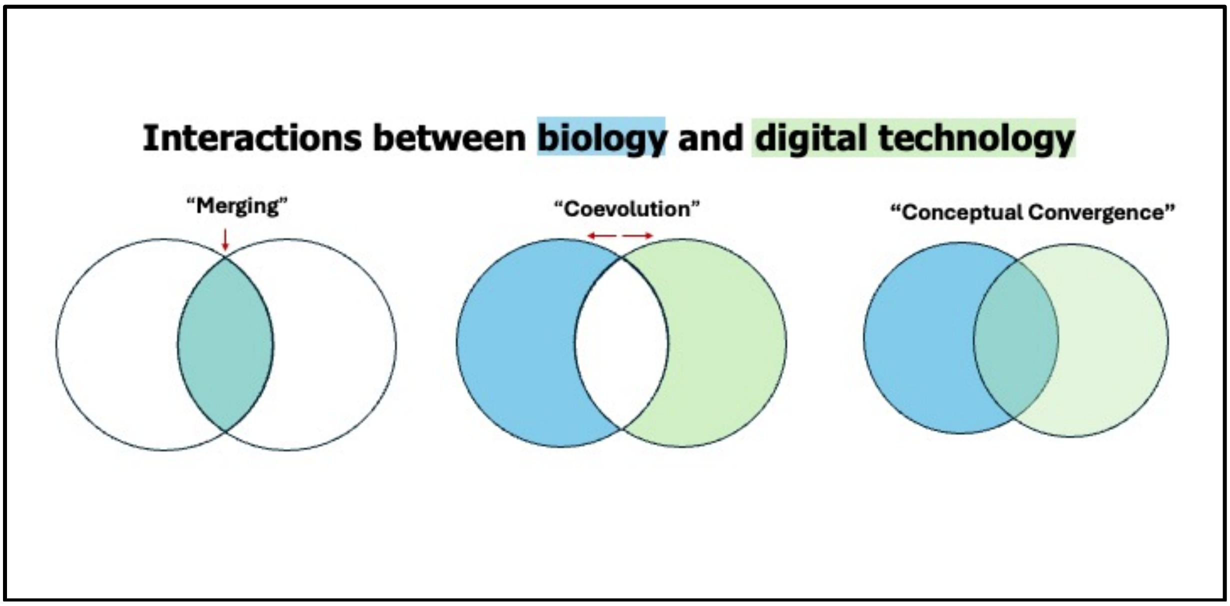
Year	Milestone	Description	Significance
1998	Consilience	E.O. Wilson's Consilience: The Unity of Knowledge proposes the integration of different scientific disciplines to achieve a comprehensive understanding of knowledge. (3)	Laid the intellectual groundwork for interdisciplinary research, encouraging the merging of biological and digital sciences.
2005	NBIC Convergence	Roco and Bainbridge introduce the concept of Nano-Bio-Info-Cogno (NBIC) convergence, highlighting the synergy between nanotechnology, biotechnology, IT, and cognitive science (2).	Paved the way for innovations like personalized medicine and brain-computer interfaces through interdisciplinary collaboration.
2015	BNCT to MANBRIC	The OECD establishes the Bio-, Nano-, and Converging Technologies (BNCT) group, which later evolves into MANBRIC, encompassing medical, additive, nano-, bio-, robo-, info-, and cogno-technologies (2).	Expanded the scope of convergence, incorporating a broader range of technologies and emphasizing ethical considerations.
2020	Biodigital Convergence	The IEC identifies the union of biological and digital systems as "biodigital convergence" (4).	Initiated a broader public and policy discourse on the implications, benefits, and risks of biodigital convergence.

4.1.2 What is Biodigital Convergence *Really*?

The IEC describes biodigital convergence as "the convergence of engineering, nanotechnology, biotechnology, information technology, and cognitive science (6)(7). Here, convergence means the "creative union of sciences, technologies, engineering, and peoples, focused on mutual benefit." This definition was crafted to be comprehensive (P2) and to emphasize the multidisciplinary nature of BDC, highlighting its potential for positive societal impact through the integration of diverse fields (P3) (5). Recognizing the challenges posed by the field's fluidity and evolving nature, the research team decided to conduct an independent literature review to dig deeper into the IEC's definition and understand how BDC is conceptualized and interpreted across a diverse cross-section of stakeholders.

Through this process, it became evident that the notion of a simple "union" between disciplines might obscure some of the intricate ways these systems interact and influence one another. To better visualize these complexities, the team developed a visual representation showcasing the interconnectedness and dynamic interplay between the various components of BDC. This visualization serves as a valuable tool for understanding the field's expansive scope. By clearly illustrating BDC's interconnectedness and dynamic interactions, it effectively sets the boundaries for what's involved, who's involved, and how standardization opportunities can be identified in the later stages of the research.

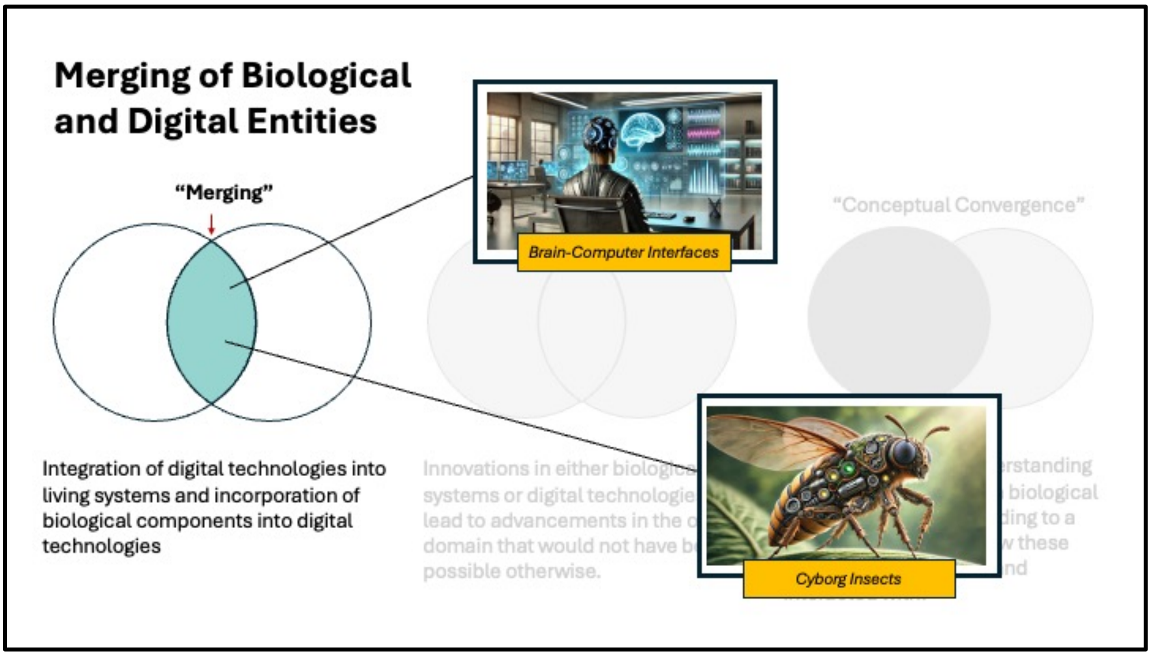
Figure 2: Highlighting the Different Conceptualizations of BDC



4.1.3 Visualizing BDC Interactions

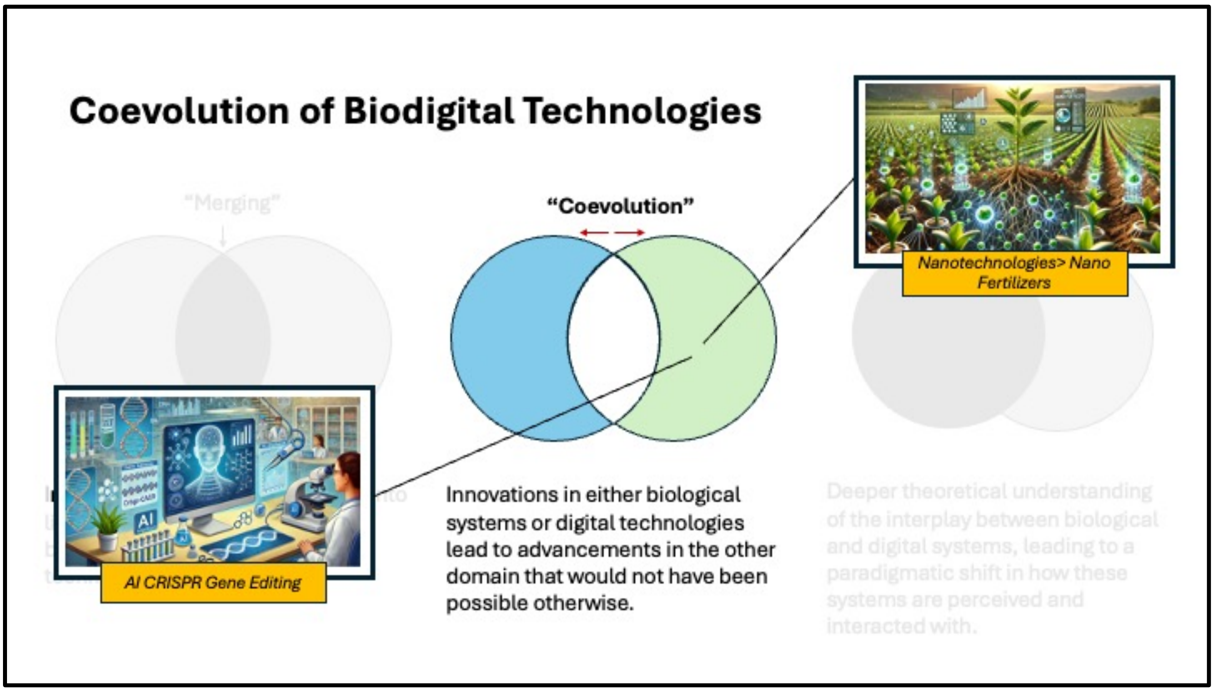
Merging refers to the physical combination of biological and digital entities. It represents the most direct form of convergence, where the boundaries between biological and digital systems are blurred or erased. Examples include embedding sensors within living organisms to monitor health in real-time and developing bio-hybrid robots that integrate living tissues with mechanical components, brain-computer interfaces, and 3D-printed organs (6)(7)(8).

Figure 3: Showing the Breakdown of BDC Merging Conceptualization



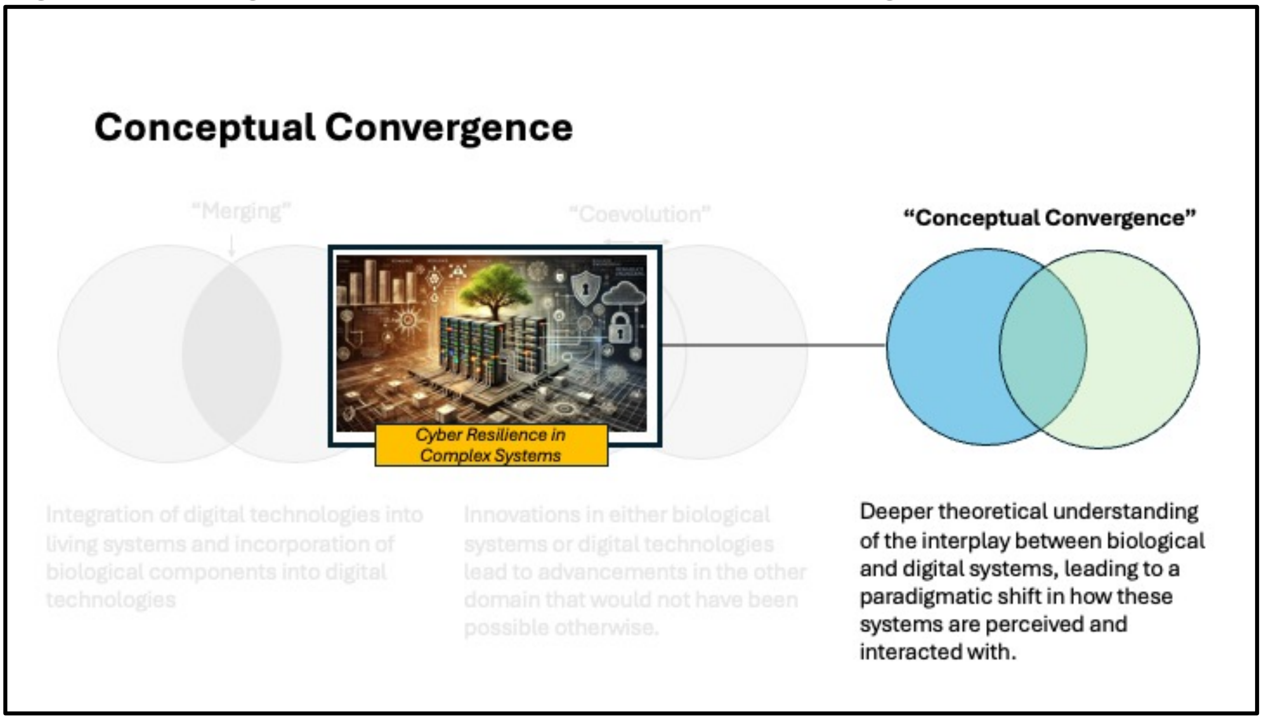
Coevolution represents how innovations in either biological systems or digital technologies lead to advancements in other the domain that would not have been possible otherwise. Examples: standalone advancements in nanotechnology have led to the creation of nano-fertilizers that release nutrients in a more controlled manner (6)(7)(8).

Figure 4: Showing the Breakdown of BDC Coevolution Conceptualization



Conceptual convergence involves a deeper theoretical understanding of the interplay between biological and digital systems, potentially leading to a paradigmatic shift in how these systems are perceived and interacted with. For instance, the study of ecological systems as complex, resilient systems can influence how we approach the development of cyber resilience within complex technological infrastructures (6)(7)(8).

Figure 5: Showing the Breakdown of BDC Conceptual Convergence Conceptualization



When presented with the three modes—merging, coevolution, and conceptualization—all interviewees confirmed that they align with their understanding of BDC. In particular, "merging" and "coevolution" were the most frequently acknowledged (P1, P2, P3).

Recognizing these modes of interaction allows for a more nuanced understanding of biodigital convergence. By moving beyond the idea of a simple "union," stakeholders can better appreciate the intricate and multifaceted relationships between biological and digital systems. This clarity is essential for guiding future research, standardization efforts, and policymaking within the nexus while acknowledging the interdependence of the individual systems

4.1.4 Breaking Apart BDC Technologies

Based on the literature, it's clear BDC technologies, at their core, are multifaceted entities composed of various interconnected components. Breaking down these technologies reveals a complex interplay of underpinning systems and platforms, intricate processes, specialized tools and intermediaries, and, ultimately, the end-stage applications that impact the real world. This deconstruction aligns with the three conceptualizations of BDC explored earlier, reinforcing the idea that these technologies, as they exist in reality, are the sum of many different types of interactions.

Table 4: Table Illustrating the Examples of BDC Components
(based on Literature Review)

Component	Examples
Underpinning systems or platforms	Cloud computing infrastructure, High-performance computing clusters, Genomic sequencing platforms, AI/ML frameworks
Processes	Bioinformatic analysis pipelines, Gene editing protocols, Tissue engineering techniques, Drug discovery algorithms
Tools and intermediaries	Biosensors, Brain-computer interfaces, 3D bioprinters, Wearable health trackers, Synthetic biology toolkits
End-stage applications	Personalized medicine, Regenerative therapies, Brain-machine interfaces, Smart prosthetics, Precision agriculture

Each component within this intricate web plays a crucial role, serving as a distinct control point that influences and contributes to the development and final deployment of BDC technologies (9). From the foundational platforms that enable data collection and analysis to the theoretical frameworks guiding their application, each element shapes BDC's trajectory and potential impact. Acknowledging these different components affects how standardization opportunities are later discussed and understood in this report.

4.1.4.1 A real example: Exoskeletons

Here, a real example of human augmentation technology is deconstructed to demonstrate the different components and areas of influence that interact within one device—an exoskeleton. This example will be revisited throughout the report.

Table 5: Deconstructing Human Augmentation to Show Components and Areas of Influence

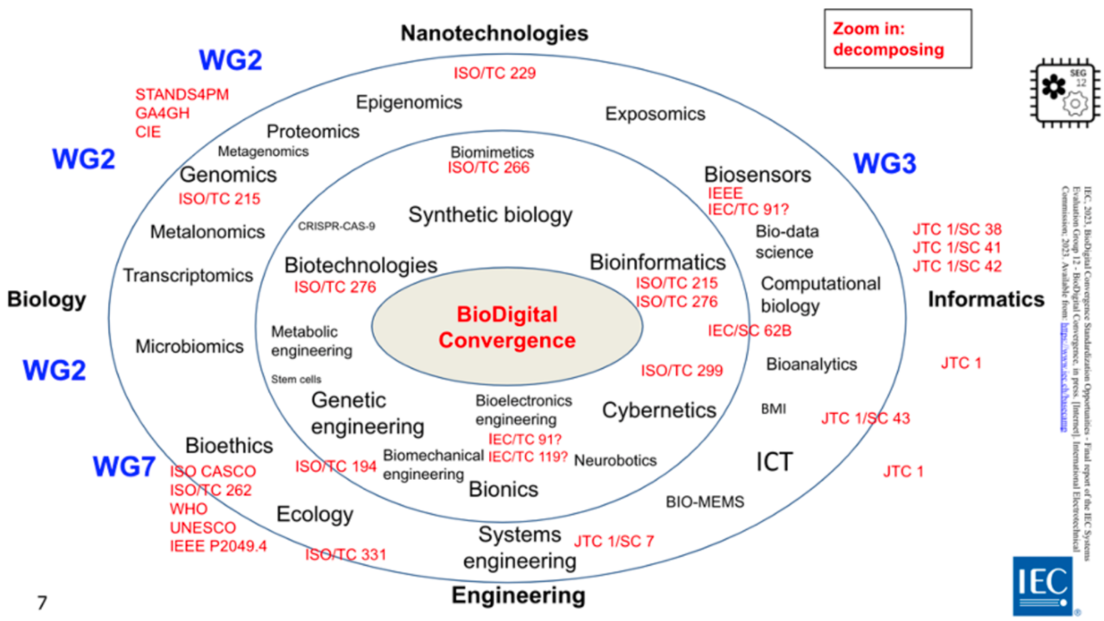
Component	Exoskeletons
Underpinning systems or platforms	Robotics, Sensor networks, Battery technology, Actuator systems, Machine learning algorithms
Processes	Motion capture and analysis, Biomechanical modeling, Control system design, Gait optimization
Tools and intermediaries	Microcontrollers, Force sensors, Actuators, Power management systems, Human-machine interfaces
End-stage applications	Rehabilitation exoskeletons (Healthcare) Military exoskeletons (Defense)

4.1.5 A Working Map of BDC Fields and Technologies

The IEC SEG 12 effectively organizes these components across different fields and sector-specific applications to form its map of the BDC landscape. It does so by:

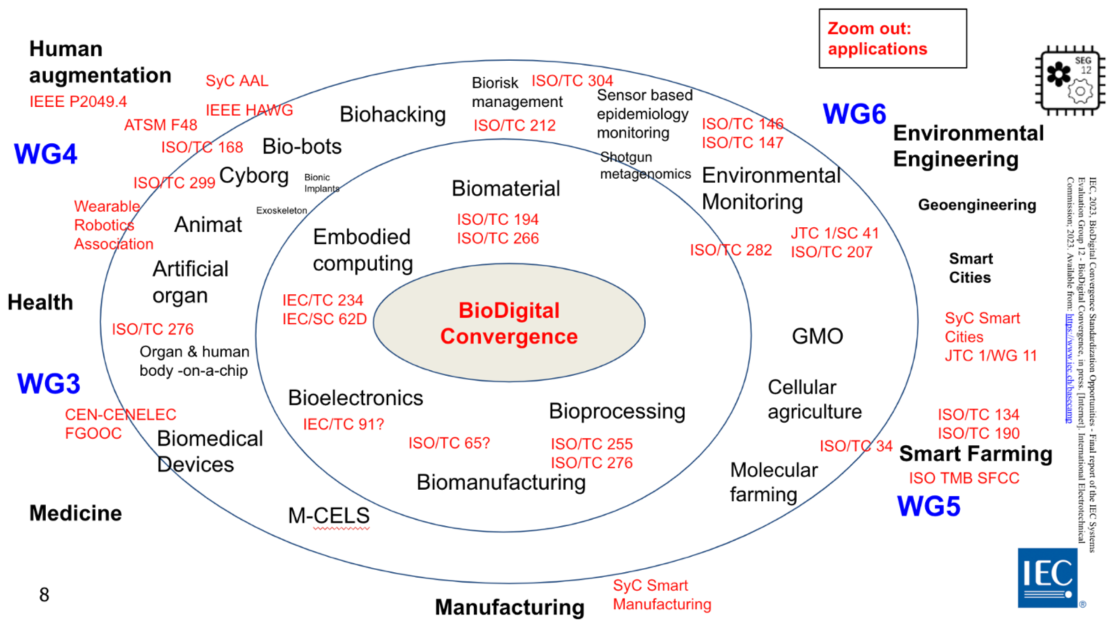
Zooming in on the foundational subfields underpinning BDC—nanotechnologies, biology, informatics, and engineering. This covers the platforms, tools, theoretical frameworks, and processes that facilitate the development of innovative BDC applications (See Figure 6 (4)).

Figure 6: Zoom in of the Subfields of BDC



Zooming out to examine how BDC applications across various sectors, including healthcare, agriculture, environmental engineering, smart farming, manufacturing, and human augmentation (See Figure 7 (4)).

Figure 7: Zoom Out of BDC Applications



4.1.6 UK Strengths within BDC Landscape

Given the expansive nature of BDC, the research team recognized the need to focus their efforts within the constraints of time and resources. To identify specific areas of emphasis with the broader domain for the UK, bibliometric analysis was conducted to measure the frequency of keywords related to BDC in academic publications since 2014, serving as a proxy for scientific output in the field. By mapping these keywords to BDC areas using terminology from the IEC framework and the UK National Vision for Bioengineering 2030, the team could pinpoint specific domains where the UK demonstrates particular strengths and research activity within the broader BDC landscape (Appendix X).

The findings highlighted that the UK's priorities in BDC are centered on its applications in healthcare and agriculture, particularly through two platforms of focus: synthetic biology and genomics.

Synthetic Biology is a field of science that involves redesigning organisms for useful purposes by engineering them to have new abilities by combining biology with engineering and informatics (10). It is revolutionizing industries from pharmaceuticals to agriculture (applied in other products) and enabling the creation of bio-based products and solutions (become products of their own) (10).

- In agriculture, this convergence leads to genetically modified crops, where digital tools and bioengineering techniques modify organisms at the genetic level, resulting in enhanced traits. This improves food security and directly impacts human health by helping reduce reliance on chemical pesticides.
- In healthcare, synthetic biology is used to engineer microorganisms, such as bacteria, to produce therapeutic compounds. A prime example is the production of insulin, which is essential for managing diabetes. This process involves using digital modeling and bioinformatics to design and optimize biological systems for medical applications.

Genomics encompasses the study of complete sets of genes and their interactions, driving advances in personalized medicine, diagnostics, and understanding genetic diseases (11). For example, babies born deaf can regain hearing after breakthrough gene therapy (P1).

- In agriculture, genomics involves using digital tools and bioinformatics to sequence and analyze crops' genomes. This enables the identification of traits like drought resistance and guides the breeding of crops with desirable characteristics.
- In healthcare, genomics facilitates personalized medicine by using digital tools to interpret an individual's genetic data, allowing for tailored medical treatments based on their genetic makeup. Integrating genomics with digital technologies, such as computational biology and data analytics, epitomizes the essence of BDC, where digital tools enhance and apply biological knowledge in previously unimaginable ways.

These areas align with national strategic goals and reflect the UK's strengths in scientific research and industry innovation (1). Anecdotally, interview participants corroborated these priorities when asked about top priorities in the UK, emphasizing the potential for the UK to lead in BDC by fostering interdisciplinary collaboration and advancing the ethical, social, and regulatory frameworks needed to support these technologies (P1, P5, P6, P7).

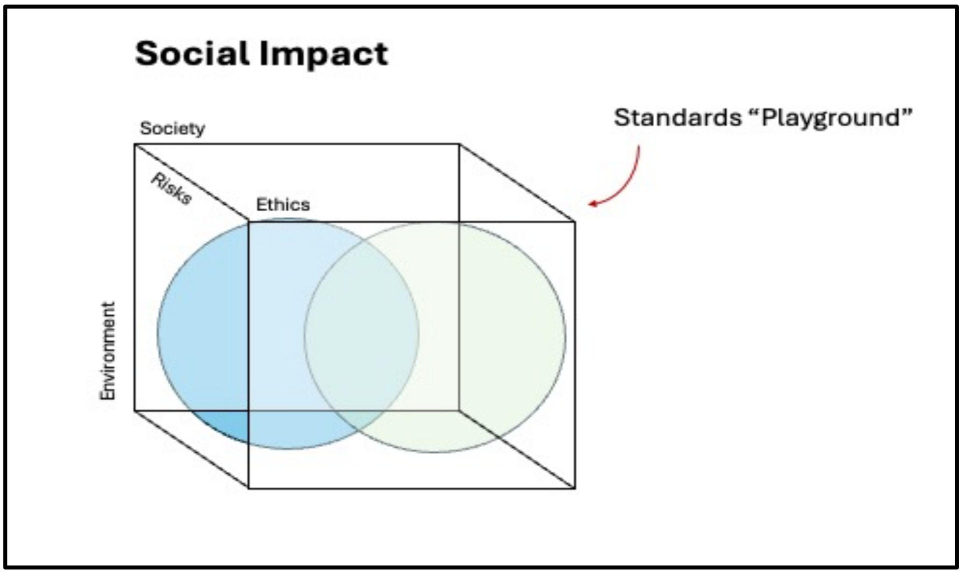
While our research primarily focuses on the broader spectrum of technologies and applications within the BDC landscape to provide a foundational understanding of the field, we will periodically revisit and delve deeper into the specific requirements, needs, and opportunities presented by Healthcare, Agriculture, Synthetic biology, and Genomics in the UK. These sectors represent key areas where BDC is poised to have an outsized transformative impact, and examining them in greater detail can help BSI further prioritize its efforts.

4.2 Ethical and Social Impact of BDC Technologies

Biodigital convergence (BDC) is fundamentally intertwined with the social and environmental fabric in which it develops. The relationship is reciprocal: BDC is both influenced by and exerts an influence on its societal context (5). The rapid development of mRNA vaccines in response to COVID-19 is a striking example of how societal needs can accelerate BDC's trajectory (5).

Returning to visualization, one can imagine the interlocking circles suspended in a cube.

Figure 8: Illustrating the Wider Environment in which BDC Conceptually Exists



Recognizing this dynamic interplay, it becomes evident that standardization needs in BDC do not occur in isolation. They're deeply embedded within this complex socio-environmental context, a space the research team aptly termed the "standards playground." Only by first understanding the broader implications of BDC can we develop standards that support safe, ethical, and effective BDC applications. The following section presents those implications.

4.2.1 Transformative Potential or Devastating Consequences?

BDC technologies present a double-edged sword: they offer transformative potential but also carry the risk of devastating consequences (4). This duality raises complex ethical questions not only about their use but also about their potential non-use (4). The research team has compiled a preliminary overview of these ethical considerations, drawing from literature, interviews, and focus groups. While not exhaustive, this overview provides a crucial foundation for the BSI team as they explore the specific role of standards in ensuring BDC technologies' safety and ethical development.

Table 6: Overview of Ethical Considerations

Grouping	Considerations	Description	Source
1. Fundamental Human Values and Rights **The core principles that define human dignity and individual liberties, primarily focusing on the individual level**	Human Dignity and Integrity	Ensuring technologies respect the intrinsic worth of individuals and do not lead to dehumanizing practices.	(12)
	Autonomy and Informed Consent	Upholding individual choice and providing clear information about potential benefits and risks.	P2, P5, P6, P7, (13) , (14)8/21/24 3:56:00 PM
	Privacy and Data Security	Protecting personal and biological data from unauthorized access or misuse.	P2, P3, P4, (13), (14)
	Equity and Access	Ensuring fair development and distribution of technologies, avoiding exacerbation of inequalities.	P5, P6, P7 (15)
2. Societal Impacts **The broader consequences of biodigital technologies on society as a whole**	Economic Disruption	Addressing potential job displacement and shifts in labor markets due to automation.	(16)
	Social Cohesion	Fostering public trust and avoiding social fragmentation or conflict.	P2, P6 (17)
	Human Enhancement	Considering ethical implications of enhancing human capabilities beyond normal levels.	(18)
	Dual-Use Concerns	Assessing and mitigating the potential for harmful use of technologies (alongside the good).	P2 , (19) (15)
3. Existential and Long-Term Considerations **The profound and potentially far-reaching implications that extend beyond immediate individual or societal impacts, altering the course of human civilisation**	Redefining the Human	Exploring the philosophical implications of merging biological and digital systems.	(20) (18)
	Technological Singularity	Considering the possibility of technologies surpassing human intelligence and the implications.	(21)

4.2.2 The influence of shared societal visions and goals

P2 first alerted the team to the influence overarching international policy frameworks like the United Nations' Agenda 2030 have on the development of BDC technologies. The team corroborated this insight through the literature.

Overarching policy frameworks like the UN's Agenda 2030 articulate a shared vision for the future, encompassing social, economic, and environmental dimensions. In doing so, they directly and indirectly shape the trajectory of BDC technologies and their impact. These frameworks not only set aspirational goals that can guide BDC innovation but also establish regulatory boundaries that constrain and direct its development. Therefore, acknowledging them is a core aspect of understanding the wider socio-environmental wrapper encasing BDC.

For example, the Sustainable Development Goals (SDGs) have catalyzed the creation of BDC applications aimed at addressing pressing global challenges, inherently guiding the development of drought-resistant crops and sustainable aquaculture technologies in response to the SDGs related to food security and sustainable agriculture (22). At the same time, international agreements such as the Cartagena Protocol on Biosafety have established rigorous risk assessment and management frameworks for the handling and transport of genetically modified organisms (23). These frameworks serve as guardrails, ensuring that the pursuit of technological advancement does not compromise biodiversity or ecological balance.

Other examples of global frameworks and their potential relationships to BDC development

- **Paris Agreement on Climate Change aims** to limit global warming and encourages the development of technologies that promote sustainable energy and resource use (24). BDC technologies like bioenergy and carbon capture and storage could play a significant role in achieving these goals.

- **The Nagoya Protocol** focuses on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization (25). It directly impacts BDC research and development by requiring researchers to obtain prior informed consent and negotiate mutually agreed terms with provider countries when accessing genetic resources.

- **The Sendai Framework for Disaster Risk Reduction** emphasizes the importance of reducing disaster risk and building resilience (26). BDC technologies like biosensors for early warning systems or bioremediation for environmental cleanup after disasters could contribute to achieving these goals.

Regional Frameworks:

- **The EU's Bioeconomy Strategy** aims to promote sustainable economic growth based on the use of renewable biological resources (27). It encourages the development of BDC technologies in various sectors, including agriculture, forestry, and healthcare.

- **The EU's AI Act** aims to regulate the development and use of artificial intelligence (AI) systems within the European Union. It categorizes AI systems based on their risk levels and imposes corresponding obligations on providers and users (28). It is likely to have significant implications for BDC, particularly in areas where AI is integrated with biotechnology or healthcare applications.

4.2.3 BDC Landscape Stakeholders

BDC is a complex and multifaceted field. This inherent complexity requires the involvement of a wide array of stakeholders, each bringing their unique expertise, interests, and concerns to the table to shape the development, deployment, governance, and usage of these technologies. This diverse group includes:

- Government and regulatory bodies (International and country-level)
- Industry and technology developers
- Academic and research institutions
- Standards development organizations (SDOs)
- Practitioners
- End-users/the public

Some of these stakeholders play a specialized role in developing standards. This is revisited in the following section of the report (§8.2).

5 Biodigital Convergence Standardization Landscape for the UK Context

Once the wider BDC landscape was mapped and understood, the research team shifted its focus to the more specific *BDC standardization landscape* to better understand what this space looks like, the directions or potential future pathways it may take, and how best to leverage standards to sustainably, ethically, and safely unlock BDC-driven opportunities.

The following section will therefore provide an analysis of the existing standardization efforts, a summary of international standardization efforts and how they interact with the UK, who the key players are and what are their roles in these standardization initiatives, an analysis of existing standards (both technical and ethical), and a discussion of what frameworks exist for developing sustainable BDC standards.

5.1 What are standards meant to achieve?

There are many ways to define a standard. For BSI, a standard is an agreed-upon way of doing something, and the content of standards can cover a wide range—from products to processes and from materials to services. More specifically, a standard is a tool that aims to establish clear, unambiguous provisions and objectives to help facilitate standard practices and relationships across a sector.(29) Standards are typically developed based on a consensus among all relevant parties.

BDC standards can unlock many opportunities and some of the prominent opportunities that were identified throughout the research are included below. Standards can significantly reduce disparities in access and knowledge, ensuring equitable distribution of the benefits of new technologies (P6). They can also build trust among end-users, which is a significant factor in promoting acceptance and successful integration of innovative technologies into society. This trust is built on the premises of transparency and accountability that standards/best practices can establish as they outline ethical manufacturing, usage practices, data collection/storage. (30) (P2)

Standards also lower costs and enhance productivity through encouraging better design and efficient data management, aligning with best practices that not only meet but exceed current ethical expectations. (31) This is achieved through standardization which can optimize processes and reduce the cost of non-quality – such as warranty claims, yield losses etc.

5.2 BDC Standardization Landscape Stakeholders

Within the BDC stakeholders' network (§7.2.3), though one tool among many, standards play a crucial role in shaping the broader BDC landscape. They act as guiding principles, ensuring the development of safe, interoperable technologies and applications across various use cases, both locally and globally (32). Moreover, standards foster collaboration within the broader BDC ecosystem and promote ethical and responsible development practices.

While every stakeholder contributes to the BDC landscape, certain entities have more specific and critical roles within the standardization process. These include:

SDOs: Central players in developing and maintaining national and international standards. Organizations like ISO and IEC lead the creation of international standards, ensuring global interoperability, safety, and ethical practice, while national standards bodies work together. These actors usually form technical working groups and committees comprised of experts who draft, review, and revise standards to ensure they are technically sound and current.

For example, some critical technical working groups and committees that play a pivotal role in the BDC standardization landscape at both international and national levels include:

- **IEC SEG 12:** This group used a systems approach to focus on emerging technical domains of BDC and coordinate efforts across various IEC technical committees. (§5.3)
- **IEC/ISO JSyC BDC:** This committee collaborates with IEC, ISO, and other SDOs using a systems approach to advance and harmonize BDC standardization efforts globally. (§5.3)
- **BSI's Biotechnologies Standards Committee BTI/1:** Represents the UK's interests in international standardization, ensuring that UK priorities are integrated into global standards. This committee comprises experts who draft and revise standards, particularly in specialized areas like synthetic biology and genomics.

Regulatory Bodies: These entities align standards with legal requirements, enforcing regulations that protect public health, safety, and ethical practices. For instance, the Medicines and Healthcare Products Regulatory Agency (MHRA) ensure that biodigital technologies meet the UK's safety and ethical standards before they are introduced to the market (33).

Industry Consortia and Trade Associations: Industry groups such as TechUK represent the interests of the UK's technology sector (34), advocating for standards that promote innovation in biodigital technologies while ensuring market access. Their involvement is crucial in aligning industry practices with national and international standards.

International Organizations: Bodies like the World Trade Organization (WTO) and World Health Organization (WHO) work to harmonize standards globally, supporting international trade and public health.

Professional Associations: These groups ensure that standards align with specific professions' practical needs and ethical guidelines. For example, the Royal Society of Biology advocates for standards that support biologists (35), while the Association of the British Pharmaceutical Industry (ABPI) focuses on pharmaceutical and biotech standards. Similarly, the NHS Confederation works to safely integrate new health technologies, including BDC, into the healthcare system. The NFU and AIC can promote sustainable and competitive standards for biodigital and agritech innovations in agriculture.

End Users and the Public: As the ultimate beneficiaries of these technologies, end users provide crucial feedback, ensuring that standards prioritize usability, accessibility, and safety.

5.3 International Standardization Initiatives Overview

International efforts in BDC standardization are primarily coordinated by the IEC and the ISO. These entities have established multiple working groups that address various aspects of BDC through a systems-based approach. This approach draws inspiration from and is grounded in a value-chain framework detailed below.

5.3.1 Value-Chain Framework

When standardizing emerging technologies like BDC, five prominent features emerge: radical novelty, relatively fast growth, coherence, significant impact, and uncertainty and ambiguity. These features capture the nature of such technologies as continuously evolving and highly disruptive. (36) BDC technologies can either enhance efficiency in the production processes of other industries or become standalone products.

A value-chain analysis is employed to better understand the standardization needs, opportunities, and potential risks associated with BDC. A value chain consists of value-adding ‘links’ between different stages of production, and it is a helpful tool for analyzing the full range of activities involved in bringing a product from its conception to its end use and beyond. (37)

This value-chain approach was first adopted by BSI in its 2017 report and was later utilized in the IEC SEG 12 report, published in April 2024, to analyze standardization related to BDC (4). It also informed the structuring of committees within the IEC and ISO, ensuring that the standardization process for BDC is effective and responsive to the full range of components within BDC.

5.3.2 IEC SEG 12 Systems Committee

In March 2023, the IEC Standardization Management Board ("IEC SMB") proposed the formation of a new systems committee dedicated to exploring BDC's emerging technical domain. This led to establishing IEC SEG 12 for BDC, a specialized systems committee with a broad scope to address BDC's unique challenges and opportunities.

Recognizing the complexity of standardizing BDC technologies, the research team found that IEC employed a systems approach rather than the conventional technical, bottom-up method. Traditionally, standards have been developed from simple technical aspects and progressed to more complex ones. However, the systems approach adopted by IEC SEG 12 is top-down, beginning with discussions and research on future industry directions to create a roadmap for current standard development.

In this capacity, the System Committee does not directly develop technical standards but coordinates with relevant stakeholders, providing guidance and direction to technical committees and other standard development organizations. This ensures that each technical standard aligns with the broader strategic goals of the BDC field.

IEC SEG 12 established six Working Groups, each tasked with exploring critical issues related to bio-digital convergence in the current standardization landscape and identifying potential standardization opportunities. These Working Groups focus on the following areas:

- Working Group 1: Reverse Engineering of Living Systems ("WG1")
- Working group 2: Life Systems and Bioengineering ("WG2")
- Working group 3: Human Augmentation Technologies ("WG3")
- Working group 4: Agricultural Bioengineering ("WG4")
- Working group 5: Environmental Bioengineering ("WG5")
- Ad-hoc Working Group: Bio-digital convergence ethical and societal considerations ("ahG7")

The structure of the committee treats ethics as separate from technical standards, with no working groups including ethics in their scope. This reflects the challenges IEC SEG 12 faced in addressing ethical issues in BDC, as noted by Interviewee 3, who remarked that "ethics can be political and can't be solved by standards." (P3)

In contrast, at the national level, interviews with key stakeholders (Interviews 1, 4, 5, and 6) revealed extensive discussions on integrating ethics into standard development. This discrepancy has raised concerns that the rapid advancement of BDC technologies may outpace the creation of clear ethical frameworks.

SEG 12 ultimately recommended a separate joint committee between ISO and IEC to address ethical considerations, acknowledging the difficulty of achieving international consensus on these issues. (P3)

5.3.1 IEC/ISO Joint Systems Committee on Bio-Digital Convergence

Following the completion of IEC SEG 12's work, a collaborative committee between the IEC and ISO, known as the IEC/ISO Joint Systems Committee on Bio-Digital Convergence (IEC/ISO JSyC BDC), was established. This committee oversees systems-level standardization activities within the domain of bio-digital convergence for both IEC and ISO. It also includes oversight of ISO/IEC JTC 1, which focuses on developing international standards in information technology, and IEC/ISO JTC 3, which addresses standardization in quantum technologies.

The scope of the IEC/ISO JSyC BDC includes facilitating outreach and engagement on BDC with ISO other SDOs and industry consortia. This work is carried out in collaboration with relevant IEC and ISO entities to effectively advance and coordinate standardization efforts in the rapidly evolving field of bio-digital convergence.

5.4 Approaches to BDC Standardization

Various approaches and frameworks exist for creating and maintaining standards. The following section will explore some of these methods and examine their relevance to BDC standardization beyond the value-chain approach, namely: responsible innovation, adaptive governance and IEC ethical principles.

5.4.1 Responsible Innovation

Responsible innovation (RI) is a comprehensive approach incorporating risk management and inclusivity into research and development, 'building on principles from science and technology studies and the ethics of technology to ensure that advancements are both socially beneficial and ethically sound'. (38)

The concept of RI is critical in the standards development of new technologies, aiming to ensure safe and equitable outcomes. Standardization and standards development are acknowledged as a core means of inserting ethics within all stages of innovation processes. (39) Standards can provide a balance by ensuring innovative efforts are matched with stringent, universally accepted and implemented ethical practices. Some examples of standards that promote RI include:

- Socially Desirable Standards: The development of standards that align with societal values by considering a wealth of factors such as health, safety, and the environment.
- Transparent and Inclusive Development Processes: Standards being developed transparently with all relevant stakeholders actively contributing and able to participate. Participatory approaches ensure developed standards are comprehensive and reflect an extensive range of needs and values.
- Standards Aligned with Broader Ethical Objectives (e.g. SDGs): The alignment of standards with overarching ethical objectives (such as those upheld by the SDGs). This ensures that standards contribute to global objectives i.e. pertaining to sustainability and social justice. (39)

However, as interviewee (P3) questioned, ethics can be a subjective lens for designing responsible standards – which can lead relativist debates around ethics and norms. However, when aligning UK national standards to broader Ethical Objectives such as the SDGs perhaps national priorities are put aside. Undermining RI in terms of national development.

Our focus group discussions indicated that the experts present believed that RI, facilitated by well-crafted standards, can enhance industry longevity, public acceptance and trust, and attract funding opportunities for BDC. This is because standards build trust and engage/improve public engagement, encourage regulatory compliance which establishes interoperability and data collection standards and encourages the diffusion of technical innovations, and attracting investments as more investors become wary of ensuring CSR and upholding ethical considerations that standards can integrate into practices. (40) RI can therefore benefit from standards as they can uphold ethical integrity to prevent past mistakes and promote long-term sustainable development and social justice in BDC (P6, P1).

5.4.2 Adaptive Governance Through Standards

Adaptive governance through standards provides a mechanism for the regulation of BDC to evolve as the technology itself evolves. This adaptiveness is crucial in managing the pace of change in BDC technologies and ensuring that governance frameworks can quickly respond to new ethical and societal challenges. Standards can help governments ensure that adaptive practices such as knowledge sharing, interoperability, data collection, and availability are foundational concepts to emerging fields such as BDC. (41) Adaptive governance, in this context, requires legitimate and fair operational structures that are recognized by those it governs, as it incorporates flexible procedures that adapt over time, allowing for ethical and societal shifts as technologies evolve. (42)

The Proportionate and Adaptive Governance of Innovative Technologies (PAGIT) framework, designed as a guideline for adaptive governance, establishes a system for addressing the dynamic nature of technology and societal needs. It emphasizes the importance of governance, accountability, participation, transparency, and integration in the development of standards, advocating that these elements are essential for creating frameworks that can adapt and respond to the ever-changing landscape of BDC. (30) Incorporating PAGIT principles, governance can become more inclusive and responsive, ensuring that the development of BDC is not only technologically sound but also ethically grounded and socially beneficial.

Interviewee 1 emphasized the importance of clear governance protocols or frameworks that enhance transparency and accountability, which in turn improve public perception and ethical practices. Moreover, our focus group discussions stressed the need for co-design and public consultation in governance processes to ensure inclusivity and responsiveness, aligning with the participatory aspect of the PAGIT framework.

The Brexit transition offers a unique case for adaptive governance through standards, where the UK has the opportunity to rapidly develop and implement standards with less external constraints (30). This scenario can foster quicker standardization in BDC, though it also presents risks if these standards diverge significantly from international norms or are hastily constructed. This context highlights the need for adaptive governance that can accommodate rapid changes while maintaining alignment with global standards, as discussed by Interviewee 5.

5.4.3 Ethics Principle-Based Approach

WG-7 has articulated a comprehensive set of principles to guide the development of ethical standards for BDC (4). The principles are grouped into five broad categories: Sovereignty of Life, Human Rights, Social Justice, Professional Ethical Responsibility, and Planetary Resilience.

Table 7: Principles and Values of Ethical Considerations (4)

Principle	Value
Sovereignty of life	Human-centric; Democracy; Autonomy; Privacy; Knowledge (right to awareness about dual use and impacts)
Human rights	Freedom; Equality; Fraternity and cooperation among people and countries; Human dignity; No torture or inhuman or degrading treatment; To mitigate bias
Social justice	Impact on trust; Fairness, Transparency; Accountability; Control (sovereignty of life and human-centric); Fair cost and fair taxation; Accessibility, Equitable justice, Strong judicial institutions
Professional ethical responsibility	"Do not harm" principle (no lethal machines); Autonomy; Responsibility; Accountability, Trustworthy; Respect for stakeholder interest; Security; Honesty; Equity; Integrity; Respect for international norms of behaviour
To promote planet resilience capability	Sustainability, Well-being; Knowledge (right to receive information about solutions and impacts); Accountability; Beneficence (machines designed to promote active assisted living and health or well-being); Explicability; Security; Innovation through harmony with people, animals and the environment; Respect for rule of law; Democracy

However, no guidance is provided for how SDOs should leverage these principles. The focus group participants responded positively when presented with the list and asked to use it to evaluate different standardization opportunities indicating the inherent value in incorporating ethical values into the creating standards to realize opportunities.

Research participants held diverse perspectives on the exact role of standards in addressing ethical concerns related to BDC. One interviewee (P3) argued that ethics is ill-suited for standardization due to its inherently subjective nature, claiming ethical principles are too variable across societies and individual beliefs to be effectively codified into a uniform standard. Other participants, however, viewed standardization as essential for promoting ethical considerations and ensuring responsible innovation in BDC (P2, P4) and cited ethics as a top priority for convening BDC committees (P4).

5.5 BDC Standardization Opportunities

The findings from our primary research highlight several critical challenges and needs within the BDC landscape, particularly in relation to standardization. These challenges present significant opportunities for organizations like the BSI and other SDOs to develop robust standards that can guide the effective, safe, and ethical implementation of BDC technologies.

The following sections explore specific needs and challenges identified through our research and outline corresponding standardization opportunities that can address these challenges effectively.

5.5.1 Training and Skills Development

One primary challenge is the need for comprehensive training and skill development. Effective training is essential for the correct application of BDC technologies. It's not just about teaching tasks, but ensuring these tasks are executed to high standards, with an understanding of relevant guidelines and protocols. For instance, operating a PCR machine requires more than basic knowledge; it requires adherence to standards that guarantee reliable results. Thus, there is a clear opportunity to develop standards for training programs, including Standard Operating Procedures (SOPs) that ensure quality and reliability in the integration of BDC technologies into clinical and commercial settings.

5.5.2 Understanding Requirements and Terms

Another critical area is the clear understanding of requirements and terms related to BDC technologies. As these technologies evolve, there is a need for standardized interpretations to avoid ambiguity, especially since existing standards often stem from traditional models that may not fully address the complexities of digital technologies. Developing standards that provide clear definitions and guidelines for interpreting and implementing requirements across various BDC technologies is crucial. These standards should include training elements to ensure stakeholders uniformly understand and apply them, reducing confusion and improving consistency.

5.5.3 Reproducibility Crisis in Research

The reproducibility crisis in scientific research poses another significant challenge, where promising research often fails to be replicated or applied in real-world scenarios. To address this, standards focusing on enhancing reproducibility through rigorous validation processes in the research and development stages should be introduced. Such standards would increase the likelihood of academic innovations succeeding in commercial or clinical applications, bridging the gap between research and practical implementation.

5.5.4 Data Sharing and Traceability

Data sharing and traceability are also vital areas where standardization plays a crucial role. Effective data sharing and traceability maximize the value of BDC technologies while ensuring data privacy and security. However, ensuring that patient data is used ethically and transparently presents challenges, particularly in R&D contexts. Developing standards that enable secure, transparent, and ethical data sharing and traceability is essential. These standards should address consent requirements, data privacy, and the ethical use of patient data, ensuring patients are informed about how their data is used and protected throughout its lifecycle.

5.5.5 Communication

Communication protocols offer another significant standardization opportunity. Effective communication is crucial when deploying BDC technologies, especially in conveying risks and benefits to various stakeholders, including patients and healthcare professionals. Establishing standards that provide clear protocols for communicating BDC technologies to different audiences is vital. These standards would ensure that communication is consistent, transparent, and tailored to specific needs, enhancing public trust and facilitating the adoption of new technologies.

5.5.6 Implementation of Other Standards or Normative Frameworks

There is also a need to enhance the implementation of existing standards and normative frameworks. Specifically, there is a lack of traceability from the concept phase to real-world product development in BDC technologies. Complementary standards that reinforce the implementation of existing frameworks, such as the AI Act, should be developed. These standards would ensure transparency, traceability, and ethical considerations throughout the design, development, and deployment of BDC technologies.

5.5.7 Development of Cost-Effective BDC Technologies

Affordability is another critical challenge, particularly in developing BDC technologies for developing regions. Ensuring these technologies are cost-effective while maintaining high standards is essential. To address this, standards that promote the development of low-cost BDC technologies without compromising quality or safety should be established. These standards could support global health initiatives by ensuring affordable technologies meet necessary technical and ethical benchmarks.

5.5.8 Sustainable Development of BDC Technologies

Sustainability in developing BDC technologies is also a pressing issue. Balancing sustainability with safety and performance is critical. Standards that guide the creation of BDC technologies to prioritize environmental responsibility while ensuring patient safety and product performance should be developed. These standards would define criteria for sustainable practices in the design and production of BDC products.

5.5.9 Patient Involvement in Decision-Making

Patient involvement in decision-making processes related to BDC technologies is another area where standardization can have a significant impact. Patients are often not sufficiently involved in decisions related to the deployment of new BDC technologies in healthcare settings. Establishing standards or protocols that ensure patient involvement in these processes, particularly when new technologies pose potential risks, would be highly beneficial. These standards would facilitate a collaborative approach between healthcare professionals and patients, ensuring that patient perspectives are integral to implementing new BDC technologies.

5.5.10 Risk Minimization Strategies in Healthcare

Finally, risk minimization strategies in the healthcare sector present an important standardization opportunity. Identifying and managing risks associated with BDC technologies is essential to protect patients and ensure the successful adoption of new innovations. Developing standards that outline risk minimization strategies, including frameworks for assessing and mitigating risks, would provide healthcare professionals with the tools to evaluate the safety of new technologies and determine their suitability for clinical use.

5.5.11 Additional Considerations

Training as a Complement to Standards: It is essential to recognize that training complements standards; without proper training, standards cannot be effectively implemented.

Shared Responsibilities: One of the challenges in BDC standardization is defining shared responsibilities across the ecosystem, ensuring that all stakeholders understand their roles in maintaining standards.

Parallel Prioritization of Standards: Participants noted that standardization efforts should not be prioritized sequentially but rather developed in parallel, as many standards are interdependent and need to be implemented simultaneously to be effective.

6 Discussion

Before providing specific recommendations to BSI for BDC standardization in the UK, the key points and takeaways from the findings and analysis are synthesized and highlighted below. This discussion informs the basis of the recommendations.

Expanding the conceptualization of BDC illuminates the diverse needs and roles of standards

- BDCs is not merely a new concept; it has evolved through various forms over a long period, demonstrating its multifaceted nature.
- Understanding the three types of convergence—merging, coevolution, and conceptual convergence—is crucial as it underscores the intricate and interdependent relationship between biological and digital systems.
- Beyond a simple union of technologies, this nuanced understanding highlights the need for standards that address the unique characteristics and challenges arising from these diverse interactions.
- Our conceptual framework seeks to go beyond considering BDC in terms of its technologies or applications and situates it within its broader socio-environmental context. For instance, without social acceptance of these technologies being encouraged throughout their development lifecycle, BDC products risk having no market traction, which could result in the field's stagnation as merely an academic or R&D concept. Therefore, this holistic understanding, considering social impact, is essential for driving realistic, equitable, and sustainable innovation that can unlock the opportunities of BDC.

Standards are pivotal in supporting the ethical development of BDC innovation

- Standards play a crucial role in promoting the social and environmental benefits of BDC technologies.
- Standards foster an environment conducive to innovation by encouraging collaboration, data sharing, and interoperability. They also address potential disparities in access and knowledge, ensuring that the benefits of these technologies are equitably distributed. Building trust among end-users is another vital function of standards. Outlining ethical manufacturing, usage practices, and data handling, standards also create transparency and accountability, crucial for fostering public acceptance of BDC innovations.

Ethics and technical standards are not separate opportunities

- While organizations like the IEC have made efforts to consider ethical implications, their approach of relegating ethics to an ad hoc committee alongside technical committees often results in principles without actionable mechanisms or guidance. It also symbolizes a separation between ethics and other standards. Based on our findings, this is a trap that needs to be avoided.

- Our initial research questions fell into that same trap and inadvertently perpetuated this separation. First, we asked: what emerging opportunities are there for standards in BDC? And *then* asked, how can standards support the ethical development of BDC? They’re one in the same.
- Regardless of their technical nature, all standards inherently shape how technologies manifest in the real world and consequently impact society and the environment. Therefore, it is crucial to view ethics, or social impact, as an integral lens through which all standards are evaluated. This involves asking critical questions such as: "What is the role of this standard in achieving benefits for society while avoiding potential challenges like inequality?"
- Furthermore, another critical dimension of standardization is their potential to support and reinforce broader normative frameworks, such as the UN Agenda 2030 (22) or the AI Act (28). BDC standards should align with these goals, ensuring that technological advancements contribute to sustainable development and do not exacerbate existing inequalities or create new ethical dilemmas. For example, in regions like Africa (P2), the development of low-cost BDC technologies is not just a market opportunity but a critical step towards achieving SDG 3 (Good Health and Well-Being) and SDG 9 (Industry, Innovation, and Infrastructure). Standards that ensure these technologies are affordable, safe, and effective can improve healthcare outcomes in underserved regions, thus supporting global health equity. Moreover, the integration of sustainability into the development of BDC technologies aligns with SDG 12 (Responsible Consumption and Production) and SDG 13 (Climate Action). Standards that guide sustainable practices in the design and production of BDC products can help mitigate the environmental impact of new technologies, ensuring that innovation does not come at the cost of ecological degradation.
- This approach acknowledges that trade-offs may exist between different ethical considerations. For example, a standard might promote interoperability and facilitate data sharing and collaboration, but it could also raise privacy concerns. By proactively addressing these potential trade-offs and documenting them transparently, we can ensure that the development and implementation of standards contribute to a more just and equitable future.

The UK has an opportunity to be a global leader in BDC and significantly influence the development of international standards

- The UK possesses a unique opportunity to emerge as a global leader in BDC, leveraging its historical strengths in genomics and synthetic biology.
- The country's existing knowledge base, collaborative research environment, infrastructure, academic institutions, and international reputation provide a solid foundation for spearheading advancements in BDC, particularly in the key areas of healthcare and agriculture.
- To fully capitalize on this potential, the UK must prioritize Responsible Innovation and Adaptive Governance within the BDC ecosystem—where standards are explicitly situated. These approaches are vital for fully realizing BDC's opportunities while mitigating the challenges that could arise from a

disconnect between ethics and standards creation. The UK can position itself as a global leader by proactively integrating social impact into BDC standardization.
- This leadership role will foster trust and acceptance of BDC technologies domestically and encourage international partnerships, knowledge sharing, and the development of global BDC standards led by the UK. By championing a responsible and ethically grounded approach to BDC, the UK can contribute significantly to shaping the future of this transformative field on a global scale.

7 Recommendations

7.1 How BSI could engage with BDC

Based on all the findings above, it is clear that the UK should establish a national committee to standardize BDC to unlock its immense potential.

In fact, The UK is currently a participating member (p-member) of the IEC system committee on BDC. This means that BSI has the ability to influence the development of BDC standards on an international scale, which is a key to help achieve policy goal of UK becoming a "science superpower" via bioengineering pillar. BSI has not fully leveraged this opportunity since it only feeds into BDC SyC through BTI/1. According to our conceptualization of BDC, the scope of BTI/1 primarily aligns with technical standards, likely covering only Layers 1 and 2 of the standard opportunities. This limited focus fails to encompass all aspects and components of BDC, particularly the ethical and social implications. Therefore, BSI should swiftly establish a dedicated committee to address the full spectrum of BDC, balancing technical and ethical/social factors to seize this opportunity.

7.2 Specific Recommendations

7.2.1. BSI should take system approach to organize a national committee

BDC as an interdisciplinary field won't fit with the original bottom-up approach, that require a top-down model for standardization focusing on an overarching system and its constituent parts. A systems approach (§5.3) from IEC would facilitate the effective and safe development of high-level interfaces and functional requirements, ensuring that the opportunities of BDC are unlocked while mitigating potential risks and challenges. Hence, the research team believe **system approach is appropriate for consideration when developing standards for BDC**.

Borrowing from the IEC systems approach, responsibilities could include:

- **Host annual forums and other communications**: The BDC Systems Committee should align with the IEC's role of fostering collaboration among various technical committees and subcommittees (TCs/SCs) working on BDC-related standards. This involves establishing clear communication channels and collaborative processes to ensure that all relevant stakeholders are working in harmony.
- **Build foundational standards**: Establish foundational standards, particularly a shared vocabulary and consistent terminology, building on the current IEC definitions. This will facilitate clear communication and ensure that all stakeholders are aligned in their understanding of BDC concepts.
- **Provide holistic view and build standardization roadmap:** Develop a comprehensive understanding of the standardization needs and gaps specific to BDC in the UK. This report is just the beginning. This involves creating a strategic roadmap that not only addresses current needs but also anticipates future developments. This roadmap should integrate the UK's National Vision for Engineering Biology, ensuring that the work of TCs/SCs is aligned with broader national goals. Initial UK Priorities have been shared in §4.1.6.

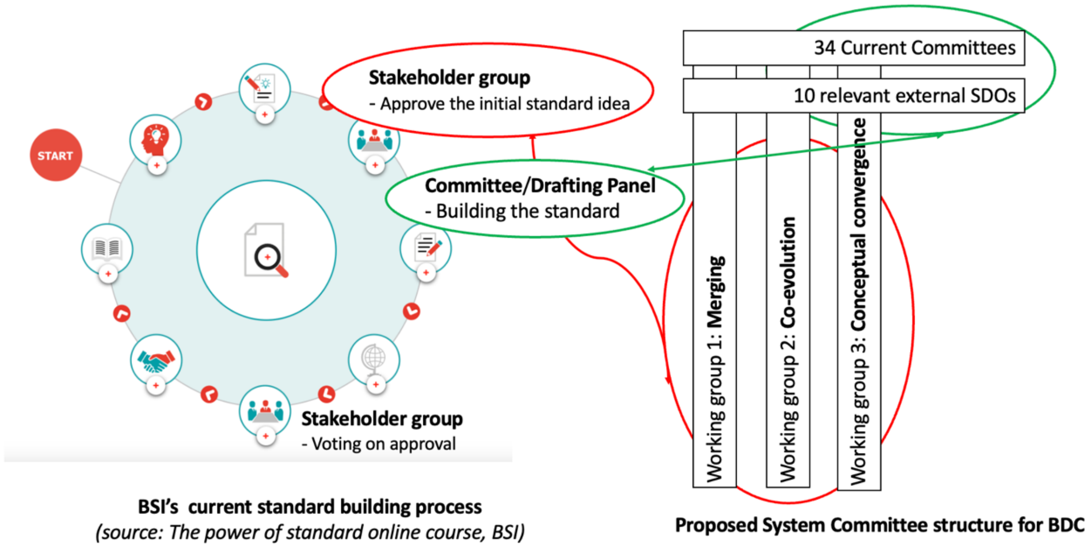
Table 8: Example of different conferences BSI can collaborate with

No	Forum Name	Organization	Focus
1	The festival of Genomics & Biodata	Front Line Genomics	cover genomics, including biodata, diagnostics, drug discovery, AI, proteomics, multi-omics and single-cell & spatial analysis
2	Synthetic Biology UK Conference	Biochemical Society	dedicate to synthetic biology, covering from foundational research to applications in industry and medicine and ethical considerations
3	Genomics England Annual Conference	Genomics England	highlight the latest in genomic research, particularly in healthcare, like personalized medicine, ethical issues, and the use of big data in genomic
4	CogX Festival	CogX	Focus on the impact of artificial intelligence (AI) and emerging technology

7.2.2. BSI could adopt the horizontal and vertical structure as the basis of its system committee

BSI can also adapt the way the IEC has structured its system committee by organizing their working groups vertically, while intersecting with R-members horizontally. The working groups discuss and establish general directions for the development of BDC, which are then fed into the R-members (including relevant TCs/SCs at IEC and ISO, as well as other related SDOs). These R-members are responsible for developing the specific standards, ensuring a comprehensive development strategy.

Figure 9: Mapping BSI current standard process with new system approach



Organizing by these layers does not also significantly change the current process to build standard at BSI. From the graph, the BSI stakeholder group functions as working groups in new approach, which include all relevant members and set the direction. These members will interact continuously with the standards development team to ensure alignment with the agreed roadmap and direction. The committee/drafting team in BSI's current process consists of independent technical committees related to BDC. Therefore, BSI will not need to spend additional time creating new processes or complicating internal procedures.

For the R-member, we have identified 34 related current committe of BSI, grouping into our conceptualization approach of BCD, and also 10 related UK specific SDOs we've identified through our analysis.

Table 9: Mapping relevant current BSI committee to become new system committee R-member

Group of standards	Committee
Group 1: Technical standards on Mergingtechnologies, underpinning systems, tools and process (13 committees)	AMT/4, IST/15, IST/33, IST/44, BCT/1, BTI/1, EH/3/4, EH/3/5, GEL/65, ICT/1, IOT/1, IST/60/1, NTI/1
Group 2: Technical standards on Co-evolution andtechnology application (11 committees)	CH/62, CH/62/2, CH/100, CH/168, CH/210/3, IST/31, IST/35, AGE/6/4, AW/34/46, TCI/100, MI/2
Group 3: Technical standards on Conceptualconvergence (Risk, Ethicals, Social Impact) (10 committees)	AMT/10/1, CH/194, CH/210, CH/210/4, CH/210/4/1, CH/304/-/1, ICT/3, IMS/1, RM/1, RM/1/-/3

Table 10: Mapping UK external SDOs to become new system committee R-member

No.	SDOs
1	Nuffield Council on Bioethics
2	UK Biobank
3	Genomics England
4	Medicines and Healthcare products Regulatory Agency
5	Biotechnology and Biological Sciences Research Council
6	Human Tissue Authority (HTA)
7	Medical Research Council
8	Institute of Biomedical Science (IBMS)
9	Agriculture and Horticulture Development Board (AHDB)
10	National Institute for Health and Care Excellence (NICE)

7.2.3. BSI could enhance consideration of social impact into the development of standards—both in its structures and the methods it uses

The IEC has chosen to treate ethics speprately. Specifically, from its organizational structure, the research team recognizes that the IEC System Committee will discuss the vision for BDC over the next 5 to 10 years solely from a technical perspective, placing ethics as an ad-hoc working group only. This result in fragmented and failing to create a sustainable ecosystem for BDC development in the future. Additionally, SEG12's proposal to establish a separate Joint Committee between ISO and IEC on ethics does not clarify how the two committees would interact.

Therefore, we recommend adpoting our findings in conceptualization of BDC to organize the working groups, as follows:

Working Group 1: This group will discuss and explore standards around **Merging** technologies and layers of technology that allows Merging to happen: underpinning systems or platform, processes, tools and intermediaries.

Working Group 2: This group will focus on improving standards on **Coevolution** technologies under both biology and digital technology and end-stage applications.

Working Group 3: This group will examine standards relating **Conceptual convergence as** the fields of biology and digital technology merge and co-evolve. It will focus more on standards related to societal perceptions, trust, and issues related to risks and ethics.

These three working groups will collaborate continuously to develop a comprehensive and sustainable vision for the BDC field. The research team also notes that the membership of these working groups should be broad, not limited to standard developers alone. It must include standard users and those with a strategic vision for BDC technologies to create a direction that is both forward-looking and practical. These are the organizations and entities that the research team has identified for stakeholder mapping (refer to $...).
The identified committees and standard bodies related to ethics will also be included when identifying R-members, ensuring ethics is embeded throughout the structure

7.2.4. Consider a case study approach: revisiting the exoskeleton example

The committee could employ a case study approach to explore real-world ethical dilemmas and challenges arising from BDC technologies across the different components, based on the 10 identified social impact (4.2.1). Analyzing these case studies will provide valuable insights that can inform the development of ethical guidelines and principles for BDC standards.

Table 11: Example of mapping social impact on different layers of exoskeleton technology

Component	Exoskeleton technologies breakdown	Social Impact
Underpinning systems or platforms	Robotics, Sensor networks, Battery technology, Actuator systems, Machine learning algorithms	Privacy and data secruity, economic disruption, social cohension
Processes	Motion capture and analysis, Biomechanical modeling, Control system design, Gait optimization	Autonomy and informed consent
Tools and intermediaries	Microcontrollers, Force sensors, Actuators, Power management systems, Human-machine interfaces	Autonomy and Informed consent, human dignity and integrity,
End-stage applications	Rehabilitation exoskeletons (Healthcare) Military exoskeletons (Defense)	Dual-use concern, human enhancement, equity and access, redefining the human

7.2.5. Continue to incorporate PAGIT Frameworks (5.4.2)

Based on the risks analysis, we recommend using the PAGIT framework at this stage to ensure risk-based regulation tailored to the assessment of each technology or group of technologies. Beyond the roles outlined by the IEC, the BDC Systems Committee should address the interplay between standards and the broader regulatory landscape in the UK, leveraging the existing PAGIT framework for assessing incremental vs. disruptive technologies. This involves considering how BDC standards can inform and support the development of adaptive and proportionate regulatory frameworks, and ensuring that standards are not developed in isolation but are integrated into national regulatory strategies at the right point in the technology's maturation

7.2.6. Explore specific methods for involving direct end users

Last but not least, establish clear processes for involving direct end-users, including patients, consumers, and other affected groups, in the standards development process is key. Currently, end-users feedback is reflected only via associations, which in sometimes doesn't fully reflect the impact of them. So we believe This ensures that the perspectives, needs, and concerns of those directly impacted by BDC technologies are considered when formulating ethical standards. This approach in fact, aligns with how BSI is moving toward the SMART standard approach, when transforming all paper-pased standard into digital platform, and interact with end-users and collect feedbacks at real-time. That's being said, this feedback-loop mechanism will be an important inputs for ethical considerations

Recommendations Summarized

- **BSI should take a systems approach to organize a national committee**
- **BSI could adopt the horizontal and vertical structure as the basis of its system committee**
- **BSI could enhance consideration of social impact into the development of standards—both in its structures and the methods it uses**
- **Consider introducing case study approaches**
- **Continue to incorporate PAGIT Frameworks**
- **Explore specific methods for involving direct end-users**

8 Conclusion

With the emergence of truly transformative technologies like those ushered in by biodigital convergence, the scope of what defines a "standardization opportunity" is fundamentally evolving.

Traditionally, standardization opportunities have been closely tied to market demands, where gaps in existing frameworks present chances for SDOs to develop and sell new standards. However, our findings suggest that a narrow market-focused view of standardization may overlook critical aspects integral to BDC technologies' responsible and sustainable development. Beyond facilitating market entry and competitiveness, standards have the potential to address human consequences and integrate social and ethical considerations into the development and implementation of BDC technologies.

Therefore, we propose that standardization opportunities should be understood more comprehensively, encompassing both market potential and the broader human, social, and ethical implications of BDC technologies. For instance, while essential for ensuring that professionals can meet industry demands, the development of standards for training and skills should also consider the broader impacts on public health and safety. Standards that incorporate ethical guidelines for training can help ensure that BDC technologies are applied in ways that protect and benefit society as a whole. Similarly, while data sharing and traceability standards are critical for building market trust, they must also address privacy concerns and ensure that data usage aligns with ethical principles and respects individual rights.

This requires a paradigm shift in how standardization opportunities are perceived and pursued, moving beyond a transactional model to one that integrates ethical considerations and human impact as core components of standardization efforts. This report has aimed to provide salient recommendations for how BSI can operationalize and be at the forefront of that paradigm shift.

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10 Appendices

10.1 Overview of Participants: Semi-structured interviews and Focus Group

The following table provides information on the interviewees background and perspective or stakeholder category. We conducted 6 interviews, identifying interviewees who had multifaceted backgrounds and perspectives in standards.

A "*" indicates an individual who also participated in the subsequent Focus Group.

Participant code and Participant Perspective.

Participant Code	Perspective/Stakeholder Category
P1	Industry
P2	SDO/Academic
P3	SDO/Academic
P4	SDO/Academic
P5	SDO/Industry
P6	SDO/Academic/Industry
P7	SDO/Industry

10.2 Interview questionnaire used during semi structured interviews

General question for all interviewee

1. Introduction and Background (2 questions – 5 mins)

1.1 Can you briefly introduce yourself and tell us how long you have been involved in the field of biodigital convergence?

1.2. What does your work at the IEC entail?

2. Understanding of Biodigital Convergence (5 questions – 20 mins)

2.1. How would you define BDC?

2.2. The IEC has defined biodigital convergence as 'merging nanotechnology, engineering, biotechnology, information technology, and cognitive science.' Can you explain the rationale behind this definition?

2.1.1. Follow-up: Is this definition commonly acknowledged within the field? Do you personally agree with it? Why or why not?

2.3. Based on our initial findings, a common theme in defining BDC is the interaction between biology and digital technologies. We have identified at least three different conceptualizations *(present the Venn diagrams: merging, coevolution, conceptual convergence – provide example)*. What are your thoughts on these ways of defining BDC?

2.4. Do these conceptual understandings influence how we identify standardization opportunities? If so, how? And how have you seen this translated into practice?

2.5. Considering the three conceptual understandings previously explained and revisiting the IEC's BDC definition, to what extent do you agree that the 'merging' conceptualization aligns with how the IEC views and understands BDC for standardization? Or are other conceptualizations also part of the IEC's understanding?

3. Future Directions & Priority Areas for Standard Development (5 questions - 20 mins)

3.1. From your perspective, which industries or technologies are advancing biodigital convergence, and which ones will be the key drivers in shaping the future landscape of the field?
Follow-up: Do you consider bioengineering as a significant part of these industries? (only if bioengineering is not mentioned)

3.2. How might these trends impact the current definition of biodigital convergence? And does IEC have a mechanism to update these terminologies regularly?

3.3. IEC has recently published a report on the standardization opportunities for bio-digital convergence. What standards do you think are most critical to the current field of biodigital convergence?

3.4. What were the main challenges or barriers to developing these standards?

3.5. Given an opportunity, what would you improve regarding standards in this area? What further actions can the IEC's SEG working groups do to help?

Customized questions for different interviewee

Interview 1,5,6:

1. What potential ethical or social implications do you foresee with emerging biodigital technologies?
2. How can standardization help address these implications? Do you have an example in the biology, bioengineering from your UK experience

3. What initiatives could be established to manage these risks and ethical concerns?

3.1. Follow-up: Who should lead these initiatives?

Interview 2:

1. Working Group [number] focuses on [topics and disciplines]. How was the decision to arrange this group made? What role did the IEC's BDC definition play in this decision? How are overlapping topics between Working Group 2 and other groups managed? Is this arrangement effective, or does it have flaws that impact its effectiveness? What would be your recommendation to make it more efficient?
2. In the recent report, your working group was the only one that stressed data as a separate standardization issue that needs to be addressed. While we believe it is applied throughout the entire field, how important do you think of bio-data standardization, and what are the steps for the UK to build its own standard?
3. Do you recognize any significant risks and ethical considerations in emerging technologies? How can standardization help mitigate those potential risks? What action should be prioritized?

Interview 3:

1. How did you decide the structure for the different working groups? What's working well? What's not working? What role did the IEC's BDC definition play in this decision?
2. In the recently published report, the WG2 decided to focus mainly on the standardization of three topics: omics, synthetic biology, and neuroscience. Can you give us a bit more insight into how you made that decision? Is there any independent study or evidence to back up these decisions?
3. The UK has long been known for its strength in genomics, DNA, and mRNA research, notably during the COVID-19 vaccination research period. What do you think of the UK's position in the field? If you were advising the UK, how would you help them identify standardization priorities in the next 5 years?
4. How important do you think of bio-data standardization? What are your assessment of the current situation of biodata standards? Do you see the improvement from 2023 when you co-published or will you change any from your recommendation? And what are the steps for the UK to build its own standard?
5. Environment is key to the 2030 Agenda (SDGs) priorities. In the latest report, as you notice you are also convener of WG6, which highlighted many SDG contribution opportunities; how do you think these opportunities should be transferred via standardization? Do you have any advice on how the UK can achieve that? The report mentions the importance of data in terms of standardization. Do you think data is a top priority?
6. Do you recognize any significant risks and ethical considerations in emerging technologies? How can standardization help mitigate those potential risks? What action should be prioritized?

Interview 4:

1. Working Group [number] focuses on [topics and disciplines]. How was the decision to arrange this group made? What role did the IEC's BDC definition play in this decision? How are overlapping topics between Working Group X and other groups managed? Is this arrangement effective, or does it have flaws that impact its effectiveness? What would be your recommendation to make it more efficient?
2. If we think of human augmentation as an industry, from research and technologies to manufacturing and distribution, which role do you think the UK can play in that supply chain? In this regard, if you were advising the UK, how would you help them identify standardization priorities in the next 5 years?

- One of the key augmentations is the social aspect. Do you recognize any significant risks and ethical considerations in emerging technologies? How can standardization help mitigate those potential risks? What action should be prioritized?

10.3 Focus group – Case Study

To set the scene during the focus group, a hypothetical case study was presented to participants.

Participants were asked to consider some of the trade-offs or tensions that might exist in how supporting standards are crafted or deployed in the real world – based on some of the ethical and social considerations presented in the case.

Scenario:
Various groundbreaking biodigital technologies have been developed recently, transforming the healthcare sector. These include Brain-Computer Interfaces (BCIs), organ-on-a-chip technology, wearable health monitors, implantable medical devices, and genomic sequencing. These technologies hold immense potential for enhancing human capabilities and personalizing medical treatments.

Setting:
Dr. Jane Thompson, a leading neurosurgeon, is facing a complex decision. Her hospital is considering implementing BCIs to improve surgical precision and patient outcomes. The BCIs would allow surgeons to control robotic surgical tools with their thoughts, potentially reducing human error and improving the success rate of complex surgeries. However, the use of BCIs raises significant concerns about mental privacy and the autonomy of surgeons. Additionally, surgeons must balance the ethical implications of using BCIs with the potential to enhance their capabilities, navigating the principle of "do no harm" and maintaining honesty with their patients regarding the risks and benefits.

In a parallel situation, a 5-year-old child named Emily has been diagnosed with a rare genetic disorder that affects her liver. Traditional treatments have been ineffective, but a new liver-on-a-chip technology offers a promising solution. This technology can replicate Emily's liver tissue and allow for customized gene therapy that could potentially cure her condition. Emily's case emphasizes the right to health and access to life-saving treatments. However, without clear standards, how can her medical team ensure she receives the best care without compromising other ethical standards?

The production and disposal of these advanced technologies also raise environmental concerns. The materials used in BCIs, organ chips, and other biodigital technologies could contribute to electronic waste and environmental pollution, conflicting with the right to a healthy environment and raising questions about the sustainability of such technologies. Without standards to govern their lifecycle, how can the hospital reconcile the need for these technologies with the right to a healthy environment and promote sustainable practices?

Moreover, the introduction of biodigital technologies may exacerbate existing inequalities in healthcare. Access to these cutting-edge technologies might be limited to wealthy individuals or countries, leaving disadvantaged populations without the benefits of these medical advancements. Without established standards, how can governments ensure equitable access to these technologies for all individuals, regardless of socioeconomic status?

Like this, many other cases will emerge in the future with the development of emerging digital technologies transforming the healthcare sector. Recognizing the urgent need for comprehensive standards in BDC, an international standardization body, the Global Biodigital Standards Alliance (GBSA), is convening a series of deliberations to address these challenges.
Departing from principles established by the International Electrotechnical Commission (IEC), such as human rights, the sovereignty of life, social justice, professional ethical responsibility, and promoting planet resilience capability, the GBSA has reunited experts from various fields, including nanotechnology, bioengineering, and healthcare, to identify standardization opportunities for the responsible use and dev of biodigital technologies.

Task:
As part of this workshop, the focus now shifts to engaging with you, the assembled experts, to delve deeper into the principles established by the IEC and understand the specific needs required to meet these principles.

10.4 Focus group – Worksheet

Focus group participants were walked through this worksheet in stages.

UCL

Part 1: Identifying Needs for Biodigital Technologies in Healthcare 25 MINUTES	Part 2: Role of Standards 10 MINUTES	Part 3: Understanding Social Impact 45 MINUTES		
In your opinion, what needs need to be met to support the development of biodigital technologies in the UK healthcare sector in alignment with the IEC principles?	Do you think standards are an effective tool to support this need? To what extent?	What is the potential size of impact on UK society if this need is unmet?	How does meeting this need align (or diverge) from the IEC principles? What are the societal benefits? Are there any tensions or trade-offs?	Does meeting this need have any cross-technology considerations? For example relevance across many different technologies and applications? Could meeting it barriers in others? Widespread benefits?
Example: Mechanics for informed consent and data privacy in biodigital applications	*Yes, standards could be effective, or used to support wider regulation. Training could also be useful*	*High*	*rights and sovereignty of life (patient autonomy, trust). However, overly restrictive data protections could end up limiting some functionality (or innovation) of technologies and subverting potential benefits.*	*Critical for all data-driven and personalized biodigital technologies*
Dr. Carole Foy				
Improved skills training in these areas (bio and digital and cross-discipline expertise)		High	Aligns with promoting well-being and knowledge by having the skilled workforce to develop and implement new healthcare innovations. supports equality and transparency	
Improved funding for translation of most promising innovation into real-world applications		High	supports economic growth of UK as well as patient benefits	
Improved mechanisms for data sharing in consistent format whilst securing data privacy		High	Supports transparency. Risk of data leaks, hacking	
Improved assessment and validation of new approaches		High	Supports "do no harm" principle	
Improved confidence and trust in new developments through clear evidence		High	As above. Reduces waste	
Biosafety and biosecurity guidance		High	Accountability, "do no harm", trust and minimising dual-use applications	
More streamlined regulatory oversight for products that cross several areas		High	Faster product approval for patient benefit, benefits to UK industry	
Improved whole lifecycle assessment of benefits e.g. financial, societal		High	Supports resilence	
Addressing the reproducibility crisis in medical research through appropriate technical standards and guidance		High	Supports resilience	
Dr. Ka-wai Wan				
Set of criteria to the groups of population that the technology is to be 'targeted' if it is not applicable to everyone	Yes - if we need to have a specific set of guidelines how the technology is to be ussed in the target population	High - the impact could be linked to othe	Equality, social justice and professional ethnical responsibility	Yes - the technology could be used for healthcare (treatment) but it could also be applied If it is applied in one field but not in another, how could this be explained to the general p in the different sectors? The benefits/risks may not be the same in all areas.
Communication of the technology / ideas to different groups of people (users, service providers and the general public)		High - as this may influence / have an ir	Patient's autonomy in understanding the technology to make a decision for their own health	same as above - some people may be familiar with the technology but in a different setti different and this needs to be communicated
How to 'de-risk' or what is the risk minimisation strategy that needs to be considered to roll out the technology?	Yes	High - the benefits/risks need to be con:	Patient's autonomy in understanding the technology to make a decision for their own health, "do not harm" principle	
Global collaboration - how to harmonise our approach?		High - if one country adopts / made a de	transparency and accountability	
Collaborative thinking / implementation across different sectors		High if not communicated properly - but	transparency and accountability	
Getting the patients to be involved in the decision-making process	Yes	High - if the product is aimed for healthc	Patient's autonomy in understanding the technology to make a decision for their own health	
Specific training for colleagues		Medium/high	Sustainability - need to have the right skillset to implement new technologies	
Dr. Shweta Agarwal				

Show side panel

10.5 Literature Review Protocol

In order to generate reading material for the literature review, a generic search engine was used, starting off by narrowing down the following key terms; "bio (-) digital convergence", "biodigital", “MANBRIC” and “NBIC”. This was done with the following question in mind: “How do different stakeholders currently understand and define biodigital convergence?”. This yielded around 176 results, within the time frame of 2018 to present.

Secondly, amongst the list of papers, those explicitly mentioning “biodigital” + “convergence” and with a broad domain approach were selected for viewing. This step was followed, by isolating papers mentioning variations of “biodigital” + an abstract that seemed relevant to our main research question.

Amongst these, we prioritized conceptual and theoretical papers while excluding those with a more sector-specific focus, aiming to provide an initial broad and expansive understanding of the field.

In order to answer our research questions, we broke down the literature review into two steps.

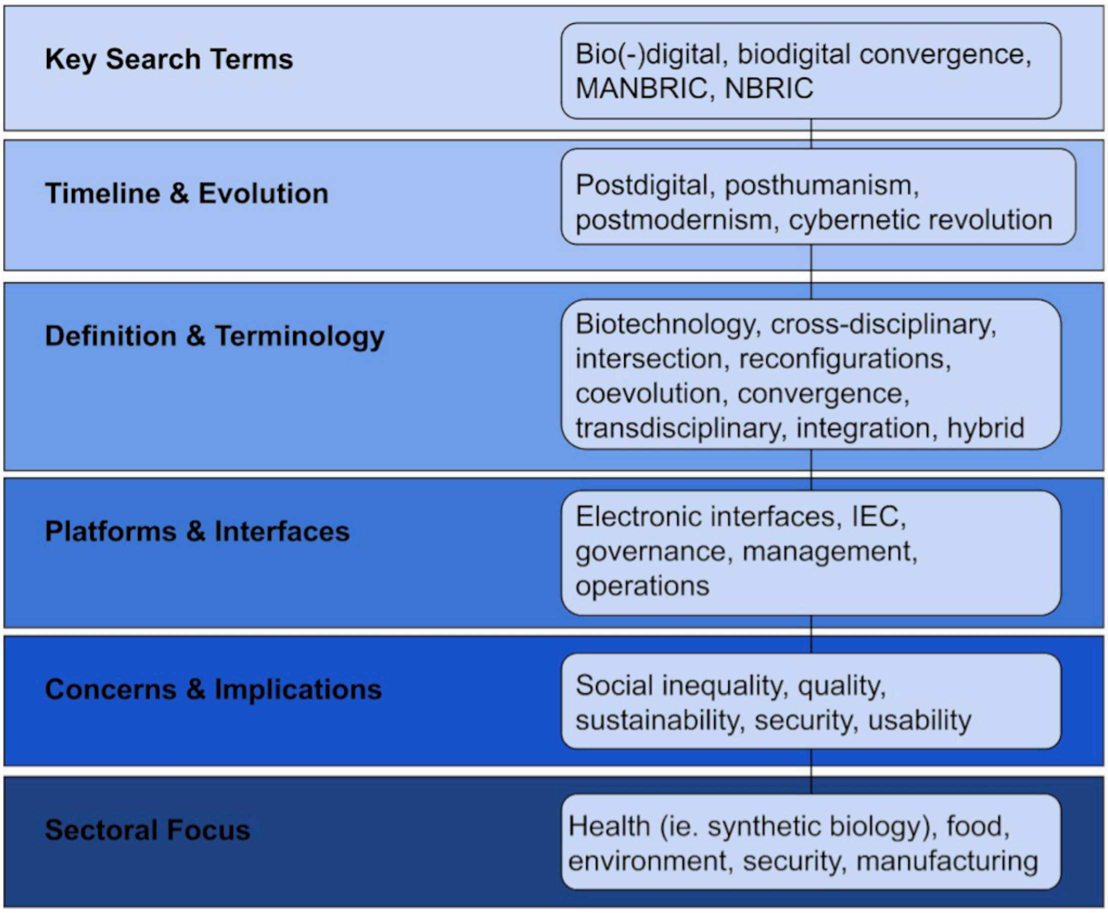
10.5.1 Part 1: Defining Biodigital Convergence

We conducted a thematic analysis, visualized in the tables below. After dividing the materials amongst ourselves, we identified 14 relevant papers providing information in five categories; (1) Timeline and Evolution, (2) Definition and Terminology, (3) Platforms and Interfaces, (4) Concerns and Implications, (5) Sectoral Focus.

This was first done by identifying the papers which provided clarifications on these topics. When one of these five themes were present within the literature, the symbol “1” was used to codify it and when the theme was absent, the symbol “0” was used instead. This visualization created a straight-forward and simple way of identifying specific sections and pieces of information, defining the boundaries of the BDC spatial and evolutionary territory.

Title	Key Terms	Timeline & Evolution	Definition & Terminology	Platforms & Interfaces	Concerns & Implications	Sectoral Focus
Postdigital Critical Pedagogy	bio(-)digital w/ convergence	0	1	0	1	1
Biobanking: A Cornerstone of Biodigital Convergence	bio(-)digital w/ convergence	0	1	1	1	1
Biodigital philosophy, supercomputing […]	bio(-)digital w/ convergence	0	1	0	0	1
COVID-19 pandemic as a trigger for the acceleration of the cybernetic […]	bio(-)digital w/ convergence	1	1	1	0	1
Indigenous perspectives on the biodigital convergence	bio(-)digital w/ convergence	0	1	0	1	1
Postdigital Critical Pedagogy and Bioinformational Social Justice	bio(-)digital w/ convergence	1	1	0	1	1
Cyber Risk Case Analysis in Wearables and Medical Devices […]	bio(-)digital w/ convergence	0	0	1	1	1
Toward Growable Robot : Exploring and Integrating Flexible […]	bio(-)digital w/ convergence	0	1	0	1	1
Portrait du personnage biodigital	bio(-)digital w/ convergence	0	0	0	0	0
A map of technopolitics: Deep convergence […]	NBIC	1	1	0	1	0
The Digital Trinity—Controllable Human Evolution […]	NBIC	1	1	1	0	0
The Postdigital-Biodigital Revolution	bio(-)digital w/ relevant	1	1	0	1	0
Biotech in China 2021 [..]	bio(-)digital w/ relevant	0	0	0	1	1
Opportunities in biotechnology	bio(-)digital w/ relevant	0	1	0	0	0

In doing so, we were then able to select specific pieces of information and sections for synthesis, grouping them under overarching themes. This enabled us to understand how relevant stakeholders conceptualize and define the BDC field, whilst doing a preliminary stakeholder mapping. However, this also helped us recognize the evolutionary changes in ethical concerns, risks and implications of these technologies and an expansion of the sectoral fields in which they developed.



10.5.2 Part 2: Bibliometrics Protocol

R Script for Bibliometrics analysis, leveraging Biblioshiny

```
install.packages("bibliometrix")
install.packages("tidyverse")
install.packages("shiny")

library(bibliometrix)
biblioshiny()
```

Search protocol

Choice of Academic Databases

Scopus and Web of Science were chosen for their extensive coverage of peer-reviewed research across multiple disciplines. Web of Science offers a wealth of technical literature on technology, whereas Scopus provides a broader social science perspectives.

Inclusion and Exclusions Criteria

The review will include:

- Literature published from 2000 to the present, aligning with acceleration ogfBDC development
- Literature representing all types of study design and methodologies (quantitative, qualitative, mixed-methods, conceptual papers, case studies, or other literary eviews) to provide a holistic assessment.
- Literature specifically published in the UK with the UK specified as the geography of interest. UK includes Great Britain, Wales, Northern Ireland, and Scotland
- Literature focuses on scientific discussion or evaluation of terms related to BDC
- It will exclude non-peer-reviewed papers, grey literature, literature in languages other than English, and book chapters where the full text is unavailable.

These exclusions ensure the focus remains on rigorously reviewed and readily accessible research.

Search strings

“bioengineering” OR “biotech*” OR “biodigital” OR "bio w/2 digital" OR “bioeconomy”

AND

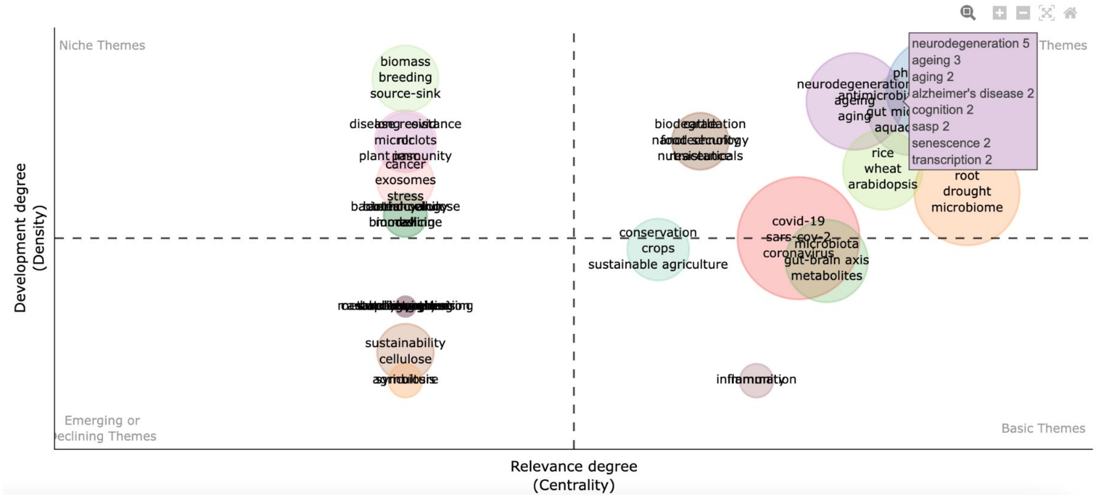
“uk” OR "united w/1 kingdom'" OR "wales" OR "scotland" OR "northern W/1 ireland"

Results

2347 papers were uploaded into Biblioshiny for mapping. Advanced keywords were extracted and mapped by Centrality and Density and to the corpus of papers.

For a given cluster, centrality is the intensity of is links to other clusters. Clusters with the most links are identified as crucial areas by the scientific communitity. Density characterizes the the strength of the links that tie words together within a cluster.

This mapping helps identify Emerging Themes and Established Themes.



Biblioshiny’s algorithms presented different sized bubbles across the spectrum. These were isolated and drilled down (i.e exploding the topline thematic bubble into specific keyword clusters). After multiple dimensions of explorations, Genomics, Synthetic Biology, Healthcare, and Agriculture were clear takeaways.