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Biobanking: A Cornerstone of Biodigital Convergence

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THE CONCEPT OF biodigital convergence has emerged in the last 20 years as a transformative paradigm that has the potential to reshape our understanding of life by not only giving us the tools to understand life but also pushing the boundaries of capabilities and functionality for all types of life through bioengineering. The term “biodigital” convergence was coined to encompass the convergence of “engineering, nanotechnology, biotechnology, information technology (IT) and cognitive science.”¹ In this context “convergence means the creative union of sciences, technologies, engineering and peoples, focused on mutual benefit; this is a process requiring increasing integration across traditionally separate disciplines, areas of relevance, and across multiple levels of abstraction and organization.”¹

Ultimately, biodigital convergence is more than a mere combination of technologies, but rather a synergistic interaction of all these fields that is creating innovations with profound implications across a wide range of domains.² Biodigital convergence eliminates the boundary between biological and digital disciplines by seamlessly integrating the biological and digital realms.

With their central role in life sciences research and development, biobanks are a prime example of the convergence of the biological and digital worlds, as they not only collect, process, and preserve biological materials but also along with rich data on the source and properties of the specimen, epidemiological data as well as analytical results.³ The variety and volume of the data required for a large biobank is thus in the realm of “big data.”⁴

The convergence is being made possible first and foremost by the rapid progress being made in IT. In the last 20 years, affordable computing power has increased by orders of magnitude, thus enabling the processing of very large volumes of high velocity data (thus the expression “big-data”). This in turn has enabled important progress in life sciences in the last 20 years. This knowledge, coupled with more sophisticated digital technologies, has in turn

enabled what we see now as important progress in biotechnology and bioengineering.

The potential of modern biotechnology and bioengineering ranges from precision genetic engineering to the bottom-up design and engineering of novel biological systems with unprecedented capabilities. Computer science and information technologies have delivered innovations at all levels, from hardware to software for knowledge integration, reasoning, and inference with machine learning and artificial intelligence (AI) techniques, to data infrastructures based on distributed ledgers and blockchain technologies that ensure trusted and secure data sharing. In particular, nanotechnology allows matter to be manipulated at the nanoscale, paving the way for creating devices that interact with biological systems at the cellular or even molecular level.^{5,6}

The areas where biodigital convergence has already made inroads are broad and come from all branches of biotechnology ranging from smart farming^{7,8} technologies which promise increased agricultural efficiency coupled with increased yields and value-added nutrients, to areas where the advantages of the extraordinarily small size of biological molecules can be used to create extremely small devices, such as nanosensors. They combine the high sensitivity and specificity of biosensors with digital recording, transmission, and evaluation of the data collected.⁹

Biodigital convergence holds great promise for transforming health care and medicine.^{10,11} It has the potential to revolutionize these fields through the use of integrated, miniaturized sensors and wearable devices to monitor health, detect risks, and diagnose diseases at an early stage. Continuous health monitoring enables early detection of abnormalities and provides real-time feedback to patients and health care professionals.

AI-powered clinical support systems offer numerous benefits, including fast and accurate diagnosis by analyzing large amounts of medical data and reducing diagnostic

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errors. They enable precision therapy based on genetic and lifestyle information and enhanced medical image analysis, leading to targeted therapies and optimized patient care. AI is also streamlining clinical processes, optimizing resource allocation, and providing expert-level diagnostic support in underserved areas.¹²

In medical research, biomedicine combined with AI technologies can accelerate drug discovery and enable precise targeting strategies by analyzing molecular data, predicting interactions, and identifying potential candidates. Together with nanotechnology, advanced drug delivery systems can be made possible.¹³

Ultimately, the convergence of biotechnology, comprehensive health data, mathematical models, and IT/AI technologies will bring us closer to creating a human digital twin, a sophisticated simulation model that will underpin true precision medicine.¹⁴

The convergence of biotechnology, digital technologies, and data science has increased the importance of biobanks in many ways. Primarily, biobanks provide the raw materials necessary to study the intricacies of human biology at the molecular level. As biodigital convergence seeks to bridge the gap between biological and digital systems, having well-curated biological samples becomes essential for researchers seeking to unravel the genetic and molecular underpinnings of various diseases and conditions. By linking biological samples to rich clinical and genetic data, biobanks facilitate comprehensive studies that can uncover biomarkers, therapeutic targets, and treatment responses.^{15,16}

In addition, biobanks are reservoirs of diverse data that are critical for the training and refinement of AI algorithms. Machine learning and AI models rely on large sets of data to identify patterns, make predictions, and uncover insights. Biobanks provide a treasure trove of data that can help train algorithms to detect subtle variations in genetic profiles, predict disease risks, and recommend tailored treatments. This interplay between biological samples and digital technologies is accelerating the development of AI-driven tools for medical diagnostics and prognostics.¹⁷

Biobanks can also play a critical role in advancing smart agriculture. They store genetic material from different plant species, helping to develop crop varieties that are resistant to diseases, pests, and environmental stressors. Preserving genetic diversity is essential for crops that can withstand climate challenges such as extreme temperatures and drought. Biobanks also conserve indigenous crop varieties adapted to local conditions, reducing input requirements. They provide valuable genetic and genomic data for informed decisions on planting, fertilization, irrigation, and harvesting. In addition, biobanks facilitate the creation of nutrient-enhanced crop varieties that improve human nutrition.^{18,19}

Biological materials and data of optimal quality are needed for all these promising developments. In recent years, due to poor prerequisites, in particular insufficient and inconsistent quality and reproducibility of the biological materials and data used, many development products have failed at an early stage or during validation.²⁰ From this insight has emerged the experience that productive and reproducible research, and thus reliable product development, is only possible with materials and samples that have been obtained and processed in a controlled and quality-assured manner. Biobanks have taken on this task and have been recognized as a reliable source of high-quality materials and data.^{3,21}

Biobanks occupy a central position in the biodigital convergence landscape. They function as foundational pillars for the integration of biological and digital systems. Their vast collections of biological specimens and the data associated with them are fueling research, paving the way for new solutions, and enabling many of the key technologies for agricultural, industrial, environmental, and medical applications.

To achieve their objectives, biodigital convergence development projects require resources of consistently high quality, assured by recognized standards. Standardization needs in biodigital convergence of life systems cover a broad spectrum, including quality of biological materials used, production and processing of biological materials, bioelectronic interfaces, data acquisition and analysis from biological entities, and machine learning algorithms.

In recent years, a number of guidelines and standards have been developed for biobanks, most notably the ISO 20387 standard for the accreditation of biobanks.²² In many other areas, however, there is still a lack of the necessary specifications. Some of the requirements are already covered by existing standards, but only at a generic level that is not always sufficient for the specific requirements of the applications.

While biodigital convergence is evolving at an incredibly fast rate, the conditions and limitations of the outcomes are still in question. Products are being developed in rapid succession and are ready to enter the market, but there is still a lack of appropriate specifications for reliability, safety, and quality of performance. This apparent deficiency motivated the International Electrotechnical Commission (IEC) to launch an initiative to identify needs and gaps in standards for bio-digital convergence technologies. A standardization evaluation group (SEG 12) was formed with a mandate to analyze the current spectrum of biodigital developments and standardization gaps but also to address ethical issues. International experts in the relevant fields were invited to provide input, which was presented and discussed in an open webinar and summarized in an IEC publication.²³

In their analysis, the experts identified five major areas where there is a critical need for standardization:

- (1) The lack of standardized, universally accepted terminology where biodigital convergence merges different domains. Creating a common understanding of the terms used is essential to ensure clear and unambiguous communication between the different domains.
- (2) The materials and methods that are used in the biotechnological processes. There are few, but urgently needed, standards for sourcing, processing, and handling the biological or ancillary materials used, the laboratory procedures employed, and the tests used to qualify the product.
- (3) The electronic interfaces that connect the biological entity to the computer system.
- (4) The quality, comparability, and usability of collected data. Inconsistent, erroneous, or implausible data, data that are poorly structured or annotated, or data that are not validated and curated will introduce significant bias and thereby invalidate the models and conclusions derived from them.
- (5) Data processing techniques that are relevant across domains and still lack general standardization, such as machine learning, deep learning, inferential statistics, and signal analysis.

As a continuation of the activities of SEG 12, it is planned to establish a Systems Committee to drive the development of the proposed standards and to set the necessary standards in close coordination with other standardization bodies.

Representatives and stakeholders of biobanks are invited to participate in the further development of guidelines and standards related to biodigital convergence. Their involvement in this process is essential for its success, as biobanks represent a central functional element of the emerging developments in biodigital convergence.

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