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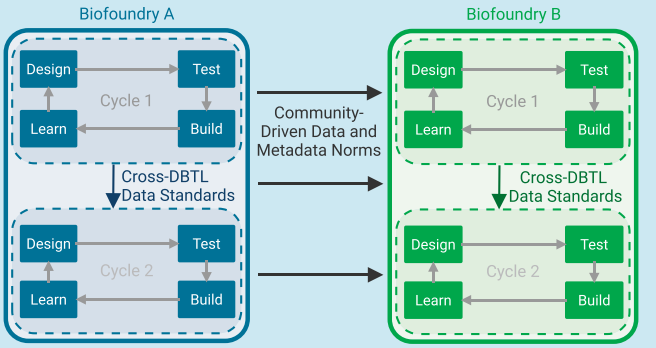
Biofoundry Data Interoperability Requires Community Action

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ABSTRACT: Biofoundries are automated laboratory platforms that execute design-build-test-learn (DBTL) cycles at scale, generating vast experimental datasets with the potential to accelerate biological discovery and grow the bioeconomy. Independent development across institutions has produced incompatible data formats and no agreed schema linking experimental metadata across cycles or between facilities, preventing aggregation for cross-institutional validation, machine learning, and reproducibility. Neither the international consortium nor the formal standards body with the mandate to act has done so, leaving an organizational gap that no technical solution has yet resolved. Closing the gap will necessitate three sequential steps: a community-driven working group to establish minimum data standards and schema, a funded international pilot cohort to test and refine them, and downstream formalization through established standards bodies. Community consensus must run ahead of, not concurrently with, formal standardization. Both the Bermuda Principles and the Protein Data Bank demonstrate that global scientific communities can establish binding data norms without a mandate, through collective agreement or through incentive structures that make compliance desirable.



KEYWORDS: *biofoundry, data standards, synthetic biology, metadata, design-build-test-learn cycle, interoperability*

INTRODUCTION

Consider two researchers working toward the same goal: one at the Agile BioFoundry in the United States[1] and another at the London Biofoundry in the United Kingdom,[2] each engineering a microbial strain to produce a biofuel precursor. When each facility constructs and verifies a strain, it logs assembly method and construct integration in its own internal format, with no shared convention linking one facility's record to the other's. Furthermore, when each facility measures the resulting strain's output, it reports yield and productivity in different units and records culture and process conditions informally, in a format that stays internal to that facility. The language and terms each facility uses are also inconsistent. The same term may describe different underlying processes at each facility, and different terms or units may describe the same one, a distinction neither researcher could know without already knowing the specific inconsistency exists. A recent publication proposing an abstraction hierarchy for biofoundry activities describes its own DNA extraction workflow assuming separate lysis and centrifugation steps, while some automated equipment performs both in one operation and requires a separate unit operation to describe the same underlying process.[3]

The two research programs could validate or extend each other's findings, but no shared schema links their records, so neither researcher can tell whether the other's results confirm, contradict, or simply differ from their own. Though technical infrastructure exists, interoperability is not currently possible because no community agreement on minimum data and metadata standards for cross-institutional exchange has been reached.

Biofoundries are automated laboratory platforms that use robotics and software to run biological engineering experiments at high speed and scale, compressing months of manual work into days. They operate through iterative design-build-test-learn (DBTL) cycles,[4] in which each round of experiments informs the next and generates large volumes of experimental data. However, independent development of biofoundries has led each institution to adopt data standards formatted for its specific instruments, experiments, and research needs.

As more biofoundries are established and novel artificial intelligence (AI) models create the opportunity to make biological discoveries at an accelerating rate depending on the volume of accessible data, now is the time for the biofoundry community to do what the genome sequencing community did in Bermuda in 1996;[5] agree on minimum data standards and metadata norms across the DBTL cycle. The path forward runs through three steps that the field already has the organizations and relationships to execute: community consensus

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on minimum standards and a schema, developed and tested by an international pilot cohort, and then formalization and compliance through national and international bodies.

THE STANDARDS GAP

The push for data interoperability and standardization spans biotechnology and engineering biology broadly, and has been grounded substantially in the FAIR (Findable, Accessible, Interoperable, Reusable) data principles ,[6] which have motivated a range of efforts to organize biological data toward those ends. In this vein, the ELIXIR organization in Europe has provided a range of data management resources that support these principles, varying by specific life science domain.[7] Similarly, the Global Alliance for Genomics and Health (GA4GH) has developed standards and policy frameworks for genomic and health data sharing.[8] Ontological efforts such as the Biolink Model and the European Viral Outbreak Response Alliance Ontology have been similarly crucial for structuring biological data, organizing broad life-science knowledge and virology-specific resources, respectively, into interoperable formats.[9,10] And the Engineering Biology Research Consortium (EBRC) has convened technical standards efforts for the global bioeconomy, identifying data standards as one of several key priorities for the bioeconomy's growth.[11] Together, these efforts reflect an ongoing, broader push toward data standardization across the biological sciences.

This broader push has reached synthetic biology and biofoundries unevenly, with different frameworks achieving different levels of adoption along the DBTL cycle. Existing frameworks address portions of the cycle: the Synthetic Biology Open Language (SBOL)[12] is a mature standard for representing biological designs, the Investigation/Study/Assay (ISA) framework[13] captures experimental context, and the Computational Modeling in Biology Network (COMBINE)[14] is a coordinating body for standards in computational biology. ISA sits alongside the life sciences' broader minimum-information tradition, which includes the Minimum Information About a Microarray Experiment (MIAME),[15] the Minimum Information for Publication of Quantitative Real-Time PCR Experiments (MIQE),[16] and the Minimum Information for Biological and Biomedical Investigations (MIBBI).[17] Those efforts specify what an experimental report must contain, while ISA specifies how that content is structured for exchange. Each of these frameworks is well suited to a particular phase of the cycle, but none is cross-cutting across the full DBTL cycle, and facility and instrumentation standardization in particular remains underdeveloped by any of them.

For biofoundries specifically, the abstraction hierarchy introduced above proposes organizing biofoundry activities into four levels, Project, Service/Capability, Workflow, and Unit Operation, to improve communication and interoperability across facilities.[3] Unlike prior standardization efforts, which were typically scoped within a single DBTL phase, this hierarchy spans the full DBTL cycle and provides explicit structure for tracking and coordinating activity both within a phase and across phases. The hierarchy, however, does not yet provide specification. It does not define which processes and elements should be standardized within each organizational level, a lexicon for those processes and elements, or a process for consolidating existing standards, such as SBOL, into the structure itself. This is particularly important as standardization requirements will likely differ across organization and process levels. The experimental level requires the most granular specification, while facility and instrumentation identifiers need far less to support interoperability. The most consequential gap sits in the build and test phases, where no agreed schema captures what was built, under what conditions, or with what outcome. Automation parameters, instrument logs, and cross-validation benchmarks also remain unstandardized. The deeper problem, however, is that biofoundry research derives its value from iteration, and no standard currently links experimental metadata from one DBTL cycle to another. A researcher cannot systematically compare outcomes across rounds, and a machine learning model cannot aggregate patterns across institutions that describe their cycles differently. Addressing this gap requires building the data infrastructure the field currently lacks, beginning with a minimum data and metadata norm for cross-DBTL exchange.

Table 1 offers an initial, illustrative structure for what a minimum cross-institutional standard could contain: elements organized across Design, Build, Test, Learn, cross-cycle linkage, and facility and instrumentation. Within each of these elements, records should further be organized by the type of information they capture, such as data type, provenance, quality, analysis, use-context, and risk, an ontological layer not visualized in the table itself but developed in adjacent work.[18] Existing frameworks relate to and cover parts of these DBTL elements, but none are expansive enough to address the full DBTL cycle or the specific needs of biofoundries. Individual biofoundries may already have strong internal data practices, including laboratory information management systems capable of tracking a construct across an entire DBTL cycle, yet the field still lacks the community-wide agreement needed for interoperability across institutions. A schema developed through community convenings and informed by biofoundry expertise is ultimately more valuable than any structure proposed here. Such a schema is likely to emerge primarily through the integration and extension of existing efforts and frameworks, rather than through the development of an entirely new standard.

The International Organization for Standardization, specifically Technical Committee 276 (ISO TC 276), which is responsible for international biotechnology standards, maintains a working group focused on data processing and integration for biotechnology broadly, though it is unknown whether that scope extends to biofoundry data exchange or DBTL metadata specifically.[19] The organizational gap is therefore bilateral; there is no formal or publicly known community consortium action on this front, nor has the formal standards body specified a biofoundry-specific scope.

COMMUNITY-DRIVEN DATA NORMS HAVE WORKED BEFORE

Community consensus has produced foundational data standards before, but not through a single mechanism. The two most instructive precedents succeeded differently: the Bermuda Principles through collective agreement ahead of any mandate and the Protein Data Bank through incentive design that made compliance desirable. Both achieved interoperability across institutions in the current research environment.

The Bermuda Principles[5] offer the clearest precedent. In 1996, the international genome sequencing community convened and agreed to deposit all sequence data into public databases within 24 h of generation. No treaty compelled the agreement. The convening itself produced the norm. That norm accelerated the Human Genome Project's completion and

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Table 1. Illustrative Data and Metadata Elements Across the DBTL Cycle, with Existing Frameworks That Relate to Each Element[a]

DBTL element	example elements	existing frameworks
design	strain and construct identity, design parameters (part composition, target function)	SBOL
build	assembly method, construct integration site and verification, robotic protocol version	none
test	instrument and assay conditions, culture and process conditions, yield and productivity units, quality-control metrics, and cross-platform measurement comparability	ISA, MIAME, MIQE
learn	analysis method applied, computational outputs and normalization steps	COMBINE
cross-cycle linkage	identifiers linking a construct, experiment, and outcome across successive DBTL cycles	ISA, Abstraction Hierarchy
facility and instrumentation	originating facility, instrument identity, calibration record; intended use and any competitive or intellectual property constraints on sharing	Abstraction Hierarchy

[a]This mapping is not exhaustive.

established open data as the foundational condition for a multibillion-dollar genomics industry. While the norm-setting goal for biofoundries is data standards, rather than data sharing, the process of using community consensus to drive innovation remains the same.

The Protein Data Bank (PDB)[20] offers a complementary mechanism. By assigning each deposited structure a four-character accession code that became a recognized publication credential, the community generated compliance through professional incentive rather than mandate. Journals required it; researchers wanted it. The biofoundry field has the same opportunity to design compliance into community recognition rather than treat it as an administrative burden.

SBOL offers a third precedent, this one internal to the field itself. Before SBOL, synthetic biology design tools developed independently, each using its own internal representation for genetic designs, so a design built in one tool could not be verified or reused in another. Community consensus solved this directly: recurring workshops brought developers of separately built tools together to agree on a shared exchange format, and by 2012 that process produced the first successful cross-tool design exchange,[21] demonstrating that community consensus already works within synthetic biology rather than only in adjacent fields. Self-driving laboratories, automated platforms operating on the same premise as biofoundries, show the same convergence happening now, with recent literature reporting large-scale automation and standardization advancing together,[22] which places the biofoundry field alongside an active standardization effort rather than at the start of one. These precedents are limited. Bermuda and the Protein Data Bank each standardized a single, relatively uniform data type. Biofoundry data is far more heterogeneous, spanning data and metadata including but not limited to diverse robotic platforms, liquid-handling systems, analytical instruments, and laboratory information management systems (Table 1). SBOL's precedent is narrower still, covering only the design phase of the DBTL cycle. None of these precedents demonstrates that a uniform data format is capable of representing the full heterogeneity of biofoundry data. What they demonstrate is the mechanism by which community convening and incentive-driven compliance can produce data norms without a mandate. That mechanism does not depend on uniform data types, which is why it can produce agreement on a minimum schema for data as heterogeneous as a biofoundry's.

INNOVATION AND REPRODUCIBILITY

The development of biofoundry data standards and norms is not only a test of feasibility but a necessity for research innovation and the development of new technologies that grow the bioeconomy.

Large-scale experiments are slow and expensive to run, which is a rate-limiting step for new discoveries. Beyond that, researchers who can rely on high-quality, reproducible data from other institutions move faster. Biofoundries[4] provide this opportunity by enabling large-scale automated experiments, and this capacity can extend further if data across biofoundries can serve as cross-institutional verification.

Additionally, for novel biotechnologies that reach the market, biofoundries are essential test beds for entrepreneurs who want to develop and then scale new products. In the same way that research is limited by the absence of data standards, new biotechnology companies that hope to develop products for the bioeconomy will be limited in their ability to verify results and reach new markets if they cannot access data from other biofoundries.

Furthermore, AI tools accelerate biological discovery in proportion to the volume and consistency of the data they train on.[23,24] Biofoundries generate exactly the kind of large, structured experimental datasets that AI models require, but fragmented formats prevent aggregation across institutions, confining the benefit of machine learning to what any single facility can accumulate independently. Standardization addresses this fragmentation, but is not by itself sufficient for AI-driven discovery; data quality, annotation consistency, experimental reproducibility, and cross-platform comparability remain necessary conditions a shared schema does not guarantee on its own.

The cost of further delay is not merely slow progress. Shared standards would decrease or avert the accumulating burden of data migration; retrofitting non-interoperable records into usable formats grows more expensive with every experimental cycle, compounding the opportunity cost of discoveries.

THE LEVER: COMMUNITY CONSENSUS AND FORMALIZATION

The path to biofoundry data standards proceeds in three steps: community consensus driven by a broad range of stakeholders, community-led programs to test the feasibility of those standards, and large-scale institutional formalization (Figure 1).

The key actor for building community consensus on biofoundry data standards is the Global Biofoundry Alliance (GBA).[25] The GBA, a consortium of more than 30 biofoundries

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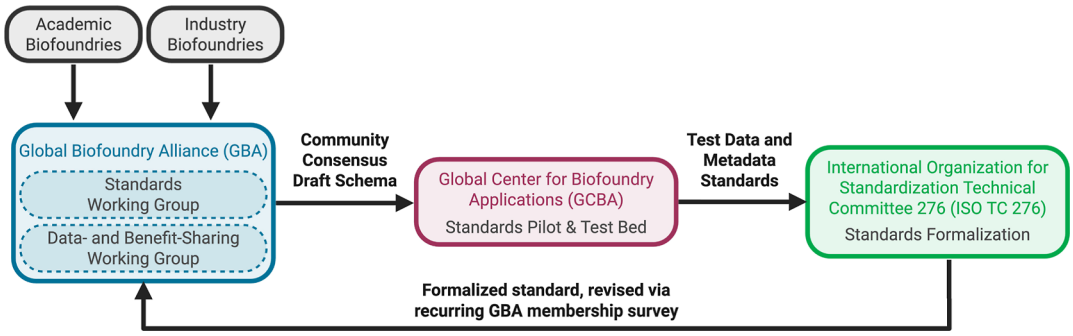


Figure 1. Proposed governance pathway for biofoundry data standardization: the GBA convenes a Standards Working Group and a Data- and Benefit-Sharing Working Group, the GCBA pilots and tests the resulting schema, and ISO TC 276 formalizes it, with revisions fed back through a recurring GBA membership survey.

founded in 2019,[4] was established to coordinate activities and share open standards, protocols, and data across member institutions. Both academic and industry biofoundries have reason to participate in biofoundry data standardization, though for different reasons. Academic biofoundries participate because interoperable data directly expands research capacity. Industry biofoundries face the same underlying data limitation and the same need for more data to grow and innovate, though competitiveness and intellectual property concerns are an important, adjacent consideration. The GBA has not yet formed a formal data standards working group with dedicated scope, deliverables, or timeline.

Following the Bermuda model, the GBA steering committee should convene a data standards working group at its annual meeting, with an explicit mandate to identify minimum data standards and metadata requirements for cross-DBTL exchange, a defined timeline, and a published output. If work toward this end is already underway informally, making that effort public would itself be a meaningful first step. A concurrent benefit-sharing and data-sharing working group should take on the competitiveness and intellectual property concerns raised above, along with issues of academic acknowledgment, running alongside rather than folded into the standards effort, with particular attention to industry-specific needs. This group would identify aspects of the schema that are particularly relevant to industry-specific standardization needs, such as those tied to commercialization and regulatory compliance, allowing a common standards framework to accommodate both academic and industrial biofoundries. This initial work is not directly funded, and will instead depend on individual institutions' willingness to invest in standardization toward their own research and innovation goals. Distributing that responsibility across engaged stakeholders, rather than concentrating it in any single actor, keeps the burden manageable and promotes broader participation.

Once community members identify the baseline standard for cross-biofoundry data exchange, the community should build a pilot program to test those standards and assess their feasibility. The Global Center for Biofoundry Applications (GCBA),[26] an NSF-funded consortium spanning seven biofoundries across five countries with an explicit mandate to develop and validate cross-national standards, provides the institutional foundation the pilot requires: funded infrastructure, cross-national membership, and a standards development mission in place. The GCBA provides resources to test community-identified standards and refine them into biofoundry data best practices. As the pilot demonstrates value, national and private funders should follow the precedent the NSF has set and fund standards work beyond the GCBA.

Only after that step can institutional formalization of standards be developed. ISO TC 276's standards carry weight that community norms alone cannot: national funders, regulatory bodies, and procurement policies can reference them as compliance conditions. Reaching that endpoint requires community standards to exist before ISO TC 276 formalizes them. ISO TC 276's three-to-five-year development timeline is too long for a field this fast-moving to wait without a standard in place, and the resulting delay would slow innovation. A community standard adopted before formalization risks becoming entrenched before a better approach is developed.

However, that risk is smaller than the alternative. Sequencing lets researchers with direct biofoundry experience set the organizing frameworks first, and the GCBA pilot cohort supplies the testing step that can catch a weak standard before ISO TC 276 formalizes it. Formalizing concurrently with community consensus, by contrast, risks the two processes diverging into incompatible standards altogether, a more difficult problem to correct than revising an entrenched community standard. Once initial standards exist, the same GBA working group should be responsible for revising them as methods and technology evolve, with the GCBA serving as a testbed for those revisions, and ISO TC 276 can then take an increasingly concurrent role, since divergence is no longer a risk once a formalized baseline is in place. Success in this pathway is measurable through the outputs already described: the GBA working group's published output, the GCBA's testing and refinement of proposed standards, and the establishment of an ISO TC 276 working group with a resulting formalized standard. Success is also measurable on an ongoing basis. National standard-setting bodies such as the United States National Institute of Standards and Technology (NIST) would develop and adopt formalized standards, and new recurring surveys of GBA membership would track adoption over time. Funders provide a third ongoing signal. Standards work funded beyond the GCBA, by the NSF or by other national and private funders, indicates that the field has recognized the standard's value independent of the original pilots.

CONCLUSION

The case for biofoundry data standards is not hypothetical. The infrastructure for community consensus exists in the GBA. The pilot cohort exists in the GCBA. The formal standards endpoint

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exists in ISO TC 276. What has not yet happened is the decision to use them together, in sequence.

This is not an aspirational goal. It has historical precedent. Community consensus has driven scientific innovation before, and the field now needs to commit to replicating that model. Further delays are not merely slowing innovation but are economically costly because of wasted resources spent repeating experiments that have already failed at other biofoundries, work required to reformat non-interoperable data, and opportunity costs of technologies that would have been developed sooner with shared standards.

The immediate next step is for the community to develop minimum data standards for cross-DBTL cycles, beginning the process that leads to formalization and adoption.

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Author Contributions

J.J. conceived and wrote this manuscript as sole author.

Notes

The authors declare the following competing financial interest(s): The author is affiliated with the Engineering Biology Research Consortium (EBRC), a co-lead partner in the Global Center for Biofoundry Applications (GCBA), which is discussed in the manuscript. The author declares no other potential conflicts of interest and accepts responsibility for the manuscript.

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ABBREVIATIONS

DBTL	design-build-test-learn
GBA	global biofoundry alliance
GCBA	global center for biofoundry applications
AI	artificial intelligence
FAIR	findable, accessible, interoperable, reusable
GA4GH	global alliance for genomics and health
EBRC	engineering biology research consortium
SBOL	synthetic biology open language
ISA	investigation/study/assay
COMBINE	computational modeling in biology network
MIAME	minimum information about a microarray experiment
MIQE	minimum information for publication of quantitative real-time PCR experiments
MIBBI	minimum information for biological and biomedical investigations
ISO TC 276	international organization for standardization technical committee 276
PDB	protein data bank
NSF	national science foundation
NIST	national institute of standards and technology

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