

INSTITUTE FOR BIOSCIENCE AND BIOTECHNOLOGY RESEARCH (IBBR)

ORGANIZATIONAL SPECIFICS

Standards Organizations:	n/a
Technical Committees:	n/a
Other Partnering Organizations:	University of Maryland – College Park, University of Maryland - Baltimore, MilliporeSigma, AstraZeneca/Medimmune, NIIMBL
Government Organizations:	NIST
Industry Sector(s) / Technology:	Biotechnology
Program / Activity Website URL(s):	https://www.ibbr.umd.edu ; https://www.nist.gov/programs-projects/nist-monoclonal-antibody-reference-material-8671 ; https://www.nist.gov/programs-projects/nistcho

STANDARDS DRIVEN PUBLIC-PRIVATE PARTNERSHIP (PPP) OBJECTIVES

PPP Drivers:

Pharmaceutical and biotech companies, academic and government institutions, and regulatory agencies and standards organizations all have an essential part to play in the bioeconomy. For this reason, the [Institute for Bioscience and Biotechnology Research \(IBBR\)](#) is structured to bring together all of the critical elements necessary to pursue solutions to major health challenges while strengthening the state and nation's bioeconomy. The IBBR serves as a catalyst to advance the understanding of biomolecular structure-function relationships which underpin biotherapeutic discovery, development and manufacture require a wide array of resources, perspectives, and expertise.

PPP Goals:

IBBR exists to foster integrated, cross-disciplinary team approaches to scientific discovery, translational development and education, and to the foster and expand the bioeconomy in the United States. IBBR works towards these goals by:

- Leveraging the collective research strengths of the partnering institutions in medicine, biosciences, technology, quantitative sciences, and engineering
- Creating innovative cross-functional collaborations that break down traditional silos and lead to pioneering research and development
- Working with a wide range of academic, government, and industry partners to move ideas from promising theory to real-world applications

Public Sector Role & Participation:

IBBR supports a dynamic research environment that facilitates interactions and collaborations among their scientists, partners, and stakeholders and promotes new research directions that complement and build on their existing strengths. In addition to research, IBBR provides resources, such as the [IBBR Commons](#), which is structured to provide a multidisciplinary environment for postdoctoral and graduate training, as well as undergraduate and high school research internships. The IBBR Commons also provides collaborative opportunities for pharmaceutical and biotech companies, other academic and government institutions, regulatory agencies, and standards organizations to be involved in research and standards development.

Implementation Methods:

IBBR hosts and holds public workshops and conferences to identify research, measurement science, and standards gaps. Typically, these events will include a mix of researchers and stakeholders from industry, academia, and other

government agencies. The IBBR facilities provide high-end technology and scientific instrumentation that support research, which makes IBBR a valuable place to host round-robin testing and other collaborations.

Measurement of Success:

Two of the most successful developments from NIST that have leveraged the IBBR partnership are the [NISTCHO](#) and the [NISTmAb reference materials](#). In most cases, biopharmaceutical companies use their own bioprocesses to manufacture formulated biopharmaceuticals for regulatory approval and eventual commercial sale that are not accessible for open-access and are considered intellectual property. The NISTCHO and NISTmAB were developed in cooperation with IBBR, [MilliporeSigma](#), and the [National Institute for Innovation in Manufacturing Biopharmaceuticals \(NIIMBL\)](#).

- NISTCHO was developed to make an industry-grade cell line openly accessible and to support innovation in CHO based industrial manufacturing. NISTCHO serves as a biomanufacturing research, educational and R&D tool. It also supports benchmarking and enables interlaboratory studies to demonstrate fit for purpose and robustness.
- NISTmAb is a monoclonal antibody (mAb) reference material that can be used in analytical research to improve measurement techniques applied to mAb biopharmaceuticals. Since its release in 2016, NISTmAb has become a ubiquitous tool for studying mAb pharmaceuticals in fundamental research, development, manufacturing, and quality analysis settings.

Since the NISTmAb has been available there have been a significant number of units sold for R&D and 113 patent applications to date that use NISTmAb as a benchmark material to demonstrate the performance of new technologies. This number is expected to rise.

Key Takeaways:

- IBBR helps pre-standardization efforts: The NISTmAb and NISTCHO helped facilitate innovation by providing an openly accessible cell-line that researchers can then use to test and improve upon. This can then lead to benchmarking of new technologies, which accelerates adoption and use of these technologies in pharmaceutical research, development, and manufacturing.
- IBBR can establish research programs based on, for example, FDA priorities, and potentially fill gaps in measurements and standards that support regulatory policy and decision making.

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