

Synthetic Biology Standards Consortium Kick-off Workshop Report

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National Institute of Standards and Technology*

Executive Summary

The kickoff meeting for the Synthetic Biology Standards Consortium (SBSC) was held at the Stanford University Li Ka Shing Conference Center on March 31, 2015. The meeting was hosted by NIST and sponsored by the ABMS program at Stanford University.

This workshop was an open, public meeting, with an invitation published in the United States government Federal Register (<https://federalregister.gov/a/2015-06839>) and distributed by email to the synthetic biology community. A total of 123 people attended the workshop, including 11 remote participants. For a list of all workshop participants see Appendix A.

The objective of the SBSC is to collectively build the metrology infrastructure to support a fully integrated, global synthetic biology enterprise. The consortium will provide safe harbor for collaborative standards development, and will maintain a broad portfolio through multiple technical working groups.

Successful working groups will be organized around a clear vision of specific metrology products—standards, including reference materials, reference data, reference methods, and documentary standards—that will enable interoperability and reproducibility.

The charge to the workshop was to identify several initial working groups with critical mass, leadership teams, and a clear path forward to deliver standards to support the growth of the bioeconomy.

During the workshop meeting participants developed *terms of reference* for SBSC working groups. Terms of reference for each candidate working group addressed problem definition, relevance, and identified specific actions for success. Volunteers proposed initial ideas for candidate working group activities during a series of panels in the morning session. Then in the afternoon, attendees self-organized for parallel working group discussions.

At the conclusion of the workshop, six working groups presented draft terms of reference. Immediate next steps for the consortium will be to establish NIST-hosted discussions (via email and conference call) for each working group to refine their terms of reference and begin developing metrology products.

For more information on SBSC activities visit <http://jimb.stanford.edu/sbcs> or contact the NIST SBSC team Matthew Munson, Sarah Munro, and Marc Salit by email at sbcs@nist.gov

SBSC Context and Operating Principles

The Synthetic Biology Standards Consortium (SBSC) will be based on a NIST-hosted consortium model, which has been successfully used to develop standards in the past. In this model, NIST will provide safe harbor for collaborative work amongst all interested parties, so that collectively we can develop technical standards solutions that will address specific problems identified by the consortium.

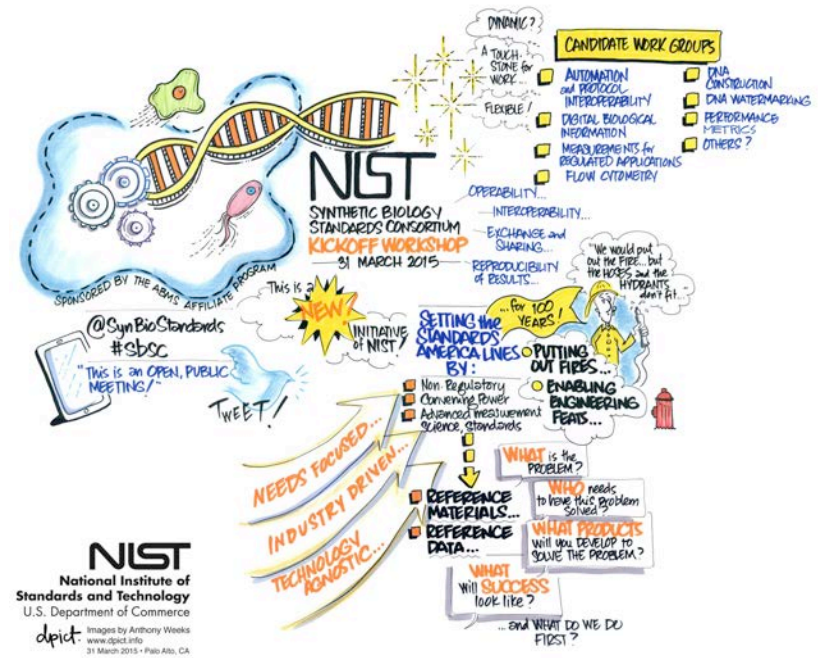
It was stated by NIST at the outset of the workshop that participation in SBSC is open, free, and voluntary. NIST will not fund work of SBSC participants. As previously stated by NIST in the Federal Register Notice, NIST reminded participants of the expectation that “no proprietary information will be shared at the workshop.” Standards developed by the SBSC will be technology agnostic and free to practice.

The broad technical portfolio of the SBSC will be established and maintained through multiple *ad hoc* technical working groups. This will allow a variety of standards development efforts to proceed in parallel. It is expected that working groups will form as needs arise and dissolve when needs are met. Decision making in the consortium will be consensus-based and data-driven. A steering body will be established to develop operating principles for the consortium.

The charge to the workshop was to identify the initial slate of working groups with clearly defined problems that could be addressed by technical standards. Working groups were asked to develop terms of reference and identify technical leaders for each of the working groups.

Appendix B contains slides presented by NIST for workshop framing.

April 24, 2015



Workshop Structure

The workshop started with panel discussions in the morning and parallel working group meetings in the afternoon. Technical working group panels were developed from volunteers who indicated leadership interest in advance (Box 1). Each panelist was asked to prepare remarks in response to these **three guiding questions**:

- What problem will this working group solve?
- Who needs this problem solved?
- What products will you develop together to solve the problem? What will success look like?

A moderated discussion followed each panel presentation, with time allotted at the end of the morning session for open technical working group pitches.

Parallel working group meetings were held in the afternoon to develop terms of reference, driven by the three guiding questions. Participants attended the group of their choosing. The groups prepared summaries to present to the consortium as a whole (Boxes 2 – 7).

Panel Discussions

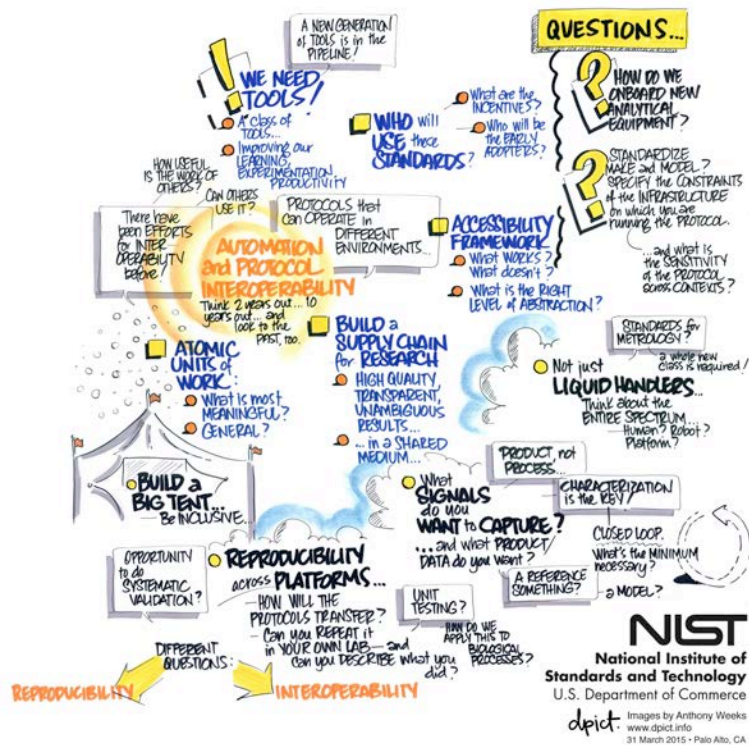
Brief summaries of each panel discussion are provided in the following subsections and Box 1 shows the names and affiliations of the volunteer panelists for the candidate working groups.

Automation and Protocol Interoperability

All panelists expressed the common goal of achieving interoperability to allow researchers to build upon each other's results. The discussion raised a number of questions around achieving this goal. With respect to minimal information standards for protocol definition, there was debate regarding the right set of information to specify and the right level of abstraction to focus on. There was discussion of establishing communications standards for instrumentation to allow automated workflows, but it was unclear how to incentivize manufacturers' participation in the standard. It was suggested that a set of benchmark protocols could be specified with a focus on the ability to achieve the desired output. Each protocol step could be specified in conjunction with a method for validating proper execution. The cost efficiency of implementing this approach for every step was questioned.

Box 1: Panel Participants

Candidate Working Group	Panelist	Affiliation
Automation and Protocol Interoperability	Will Canine	Opentrons
	Tim Gardner	Riffyn, Inc.
	Max Hodak	Transcriptic
	Eric Klavins	University of Washington
	DJ Kleinbaum	Emerald Therapeutics, Inc.
	Morgan Paull	Stanford Bioengineering
Flow Cytometry	Sean Ward	Synthace, Ltd.
	Jake Beal	Raytheon BBN Technologies
Digital Biological Information	Traci Haddock	iGEM
	Nathan Hillson	Joint BioEnergy Institute
	Richard Kitney	Imperial College London
Performance Metrics for Engineered Strains	Nicholas Roehner	Boston University
	Herbert Sauro	University of Washington
	Patrick Boyle	Ginkgo Bioworks
Measurement for Regulated Applications	Amor Menezes	University of California, Berkeley
	Paul Freemont	Imperial College London
	Todd Kuiken	Woodrow Wilson Center
DNA Construction	Megan Palmer	Stanford
	Connor Dickie	Synbiota, Inc.
	Michael Fero	TeselaGen Biotechnology
Security	Enoch Yueng	Caltech
	William So	FBI

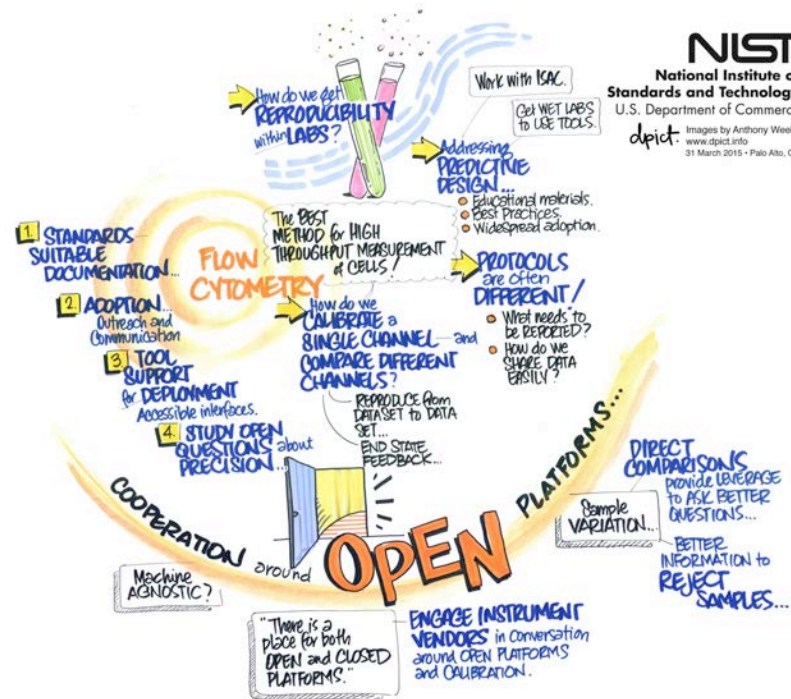


Flow Cytometry

This panel focused on the extension and dissemination of existing flow cytometry standards for single channel calibration to multiple channels. This updated standard will allow for quantitative cross-correlations on a cell-by-cell basis. Four key areas for improvement were identified: improving documentation for existing standards, accelerating adoption through community outreach, development of software tools to simplify analysis, and investigation of open questions about precision of calibration across multiple channels. Minimal information standards for the reporting of cytometry protocols were proposed. The role of developing machine agnostic

April 24, 2015

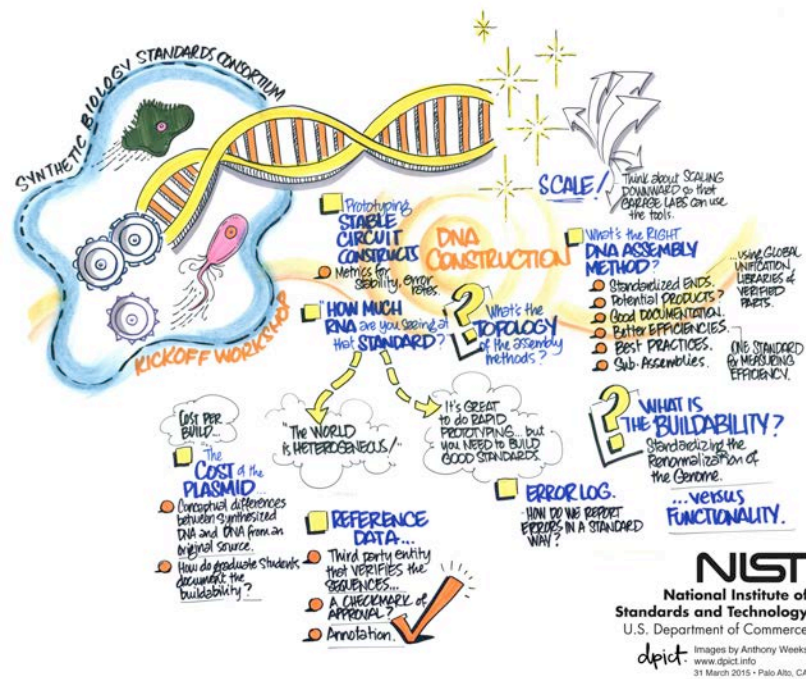
calibration procedures was explored as a mechanism to allow comparison of results across space, time, and technology platforms.



DNA Construction

The panel discussion focused on implementation of best practices for assembling of DNA into larger constructs, rather than the chemical synthesis of oligos. The primary goal is the transformation of cloning and sub-cloning from an "art form to science". Several areas that would benefit from standardized methods were discussed including standard ends for sub-assemblies, methods of reporting synthesis or assembly errors,

and characterization of buildability with respect to function. The burden of re-sequencing parts ordered from various repositories was noted. It was suggested that a third party could verify the sequence of deposited parts, and that this entity could also be responsible for annotation.

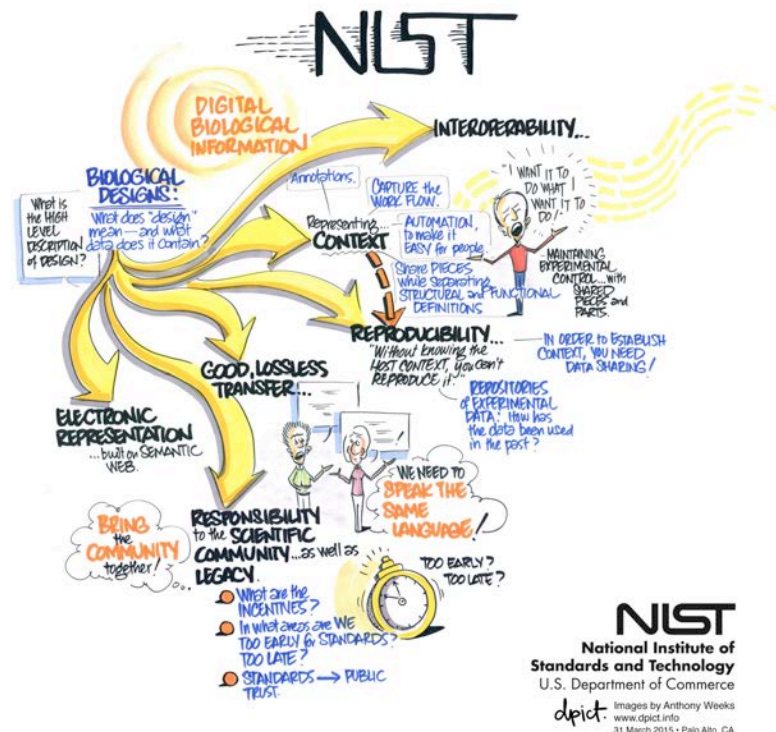


Digital Biological Information

These panelists agreed that biological design specifications must include not only the intended function, but also information about context to enable reproducibility. Discussants proposed that data sharing through the expansion and curation of experimental data repositories is critical to develop context specifications. Setting a single information standard format was far less important than enabling

interoperability and seamless integration between existing standards and data repositories.

A question was raised during this panel discussion about the appropriate timing for developing standards. Is there a concern about creating international conflicts on standards? It was pointed out that due to the long time scales involved in producing standards it is important to bring people to the table early and use face-to-face interactions to build trust. The point was also made that standards can be flexible and scaled over time. Panelists proposed that the time has come for adding context specifications to digital biological information standards.



Performance Metrics for Engineered Strains

The panelists addressed different needs; one calling for reference objects, genetics parts, and libraries of strains, the other focusing on the standardization of reporting on part characteristics in support of predictive design. Both discussed the role of context on the performance of these reference objects. These two approaches are not in conflict with each other, but are at different levels of abstraction. *The need to establish methods for characterizing performance for contractual/commercial purposes was also discussed.*



Measurements for Regulated Applications

This panel discussion focused on the need to develop public acceptance for synthetic biology, and achieving this by cultivating a public perception that the technology is safe. From the perspective of detection of an engineered organism after a release the discussion was framed in terms of three questions: What is it? Where is it? Does it matter? The final

April 24, 2015

question was set aside as primarily a question of regulation rather than measurement. The need for field methods to be robust to variations in protocol and sampling was noted. Watermarking of DNA was suggested as a measurement strategy that would allow environmental tracking. Concern was expressed about allowing regulations to get ahead of measurement science.

Open Pitch on Security

It was suggested that all the working groups consider issues related to security in their work. It was proposed that an evolving framework allowing for supply chain resilience would be applicable to all practitioners regardless of scale.



Working Group Summaries

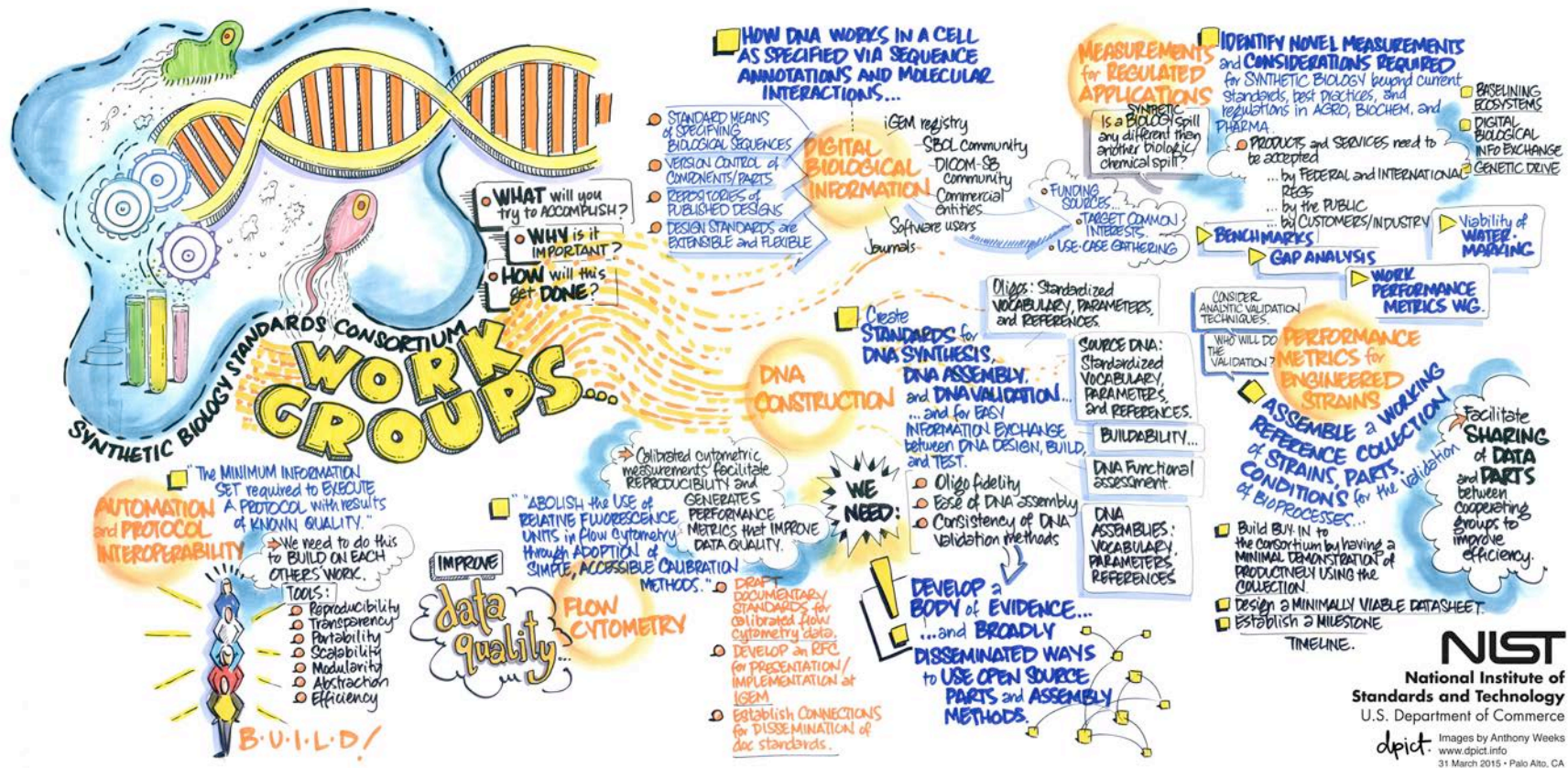
In the afternoon, six WGs from the pitch session met in parallel to define terms of reference. Participants split into WGs based on individual interest. Leadership of each working group emerged organically. These conversations were driven by the guiding questions:

- What problem will this working group solve?
- Who needs this problem solved?
- What products will you develop together to solve the problem? What will success look like?

The groups were provided guidelines and framing questions to help in crafting their terms of reference. The groups considered the following questions as a basis:

- What has to be achieved?
- Who will take part in it?
- How will it be achieved?
- What is the time frame?

Groups met for ninety minutes to discuss these questions and prepared terms of reference to present to the consortium as a whole. The contents of the reports from the groups are illustrated below and in Box 2 – 7.



Box 2: Automation and Protocol Interoperability Terms of Reference

We will aim to:

define the minimum information set required to execute a protocol with results of known quality

Our aim is important because:

we need to do this to build on each others' work. Tools need to have reproducibility, transparency, portability, scalability, modularity, abstraction, and efficiency.

Our approach will be to:

- Generate a minimum information set for appropriate atomic lab operations expressed as a controlled vocabulary
 - Generate a suite of benchmark experiments
 - Develop Quality Metrics
 - Demonstrate benchmarks on multiple platforms
-

Box 3: Flow Cytometry Terms of Reference

We will aim to:

abolish the use of relative fluorescence units in flow cytometry through adoption of simple, accessible (and established) calibration methods.

Our aim is important because:

calibrated cytometric measurements facilitate reproducibility and generate performance metrics that improve data quality.

Our approach will be to:

- Draft documentary standards for calibrated flow cytometry data
 - Develop an RFC for presentation/implementation at IGEM (May/June)
 - Establish connections for dissemination of documentary standards and RFC
 - BioBricks, DNA 2.0, ACS SynBio, Nature family, BioConductor.org
-

Box 4: Measurements for Regulated Applications Terms of Reference

We will aim to:

identify what novel measurements and considerations are required for synthetic biology beyond current standards, best practices and regulations in agro/biochemistry/pharma.

Our aim is important because:

products and services need to be accepted by federal and international regulations, customers/industry, and the public

Our approach will be to:

- Benchmarking current practices & regulatory environment for all products/applications
 - Gap analysis – understanding latest state of the art for measurement
 - Is sequencing adequate for measurement as a first step – with NIST maintaining standards of known sequences
 - Working with Performance Metrics WG – genetic ‘drift’ (mutations in growth, populations, etc. over the course of production); secondary metabolites
 - Investigate viability of ‘watermarking’ – technically, implementation and public relations
 - Need to have discussion with regulators
 - “Baselining” ecosystems – for measurement of effects and ‘unnatural’ perturbations
 - Digital Biologic information exchange
 - Genetic Drive – to manipulate genetics of wild populations
 - Is a ‘synthetic biology spill’ different than any other biologic/chemical spill?
-

Box 5: Digital Biological Information Terms of Reference

We will aim to:

- Standard means of specifying biological sequences
 - How DNA works in a cell as specified via sequence annotations and molecular interactions (context dependence)
 - Version control of components/parts
 - Repositories of published designs (successful or not)
-

Our aim is important because:

design standards need to be extensible and flexible.

Our approach will be to:

- Identify funding sources
 - Target common
 - Possible for NIST to facilitate use-case gathering + special issue discussing outstanding standard and software needs/use-cases
 - Participants:
 - iGEM registry community
 - SBOL community
 - DICOM-SB community
 - Biomaterials Repositories
 - Commercial Entities
 - Users of software
 - Journals
-

Box 6: DNA Construction Terms of Reference

We will aim to:

create standards for DNA synthesis, DNA assembly and DNA validation, and for easy information exchange between DNA design, build and test.

Our aim is important because:

oligo fidelity, ease of DNA assembly, and consistency of DNA validation methods are needed to accelerate progress in synthetic biology.

Our approach will be to:

- Oligos: Standardized vocabulary, parameters and references
 - Source DNA (whether synthesized or natural): Standardized vocabulary, parameters and references
 - DNA Assemblies: Standardized vocabulary, parameters, protocols, to quantify the efficiency of DNA part assembly
 - How many clones (X) do I need to pick to get sequence validity of (Y)%?
 - What does “sequence verified/validated mean”
 - Build-ability: Standardized error and warning reporting.
 - DNA Functional Assessment: Standards by which functional measurements (dependent variables) can be related to sequence and sequence context (independent variables)
 - Buildable while retaining function.
 - Broadly disseminated ways to use open source parts and assembly methods.
-

Box 7: Performance Metrics for Engineered Strains Terms of Reference

We will aim to:

assemble a reference collection of strains, parts, and conditions for the validation of bioprocesses

Our aim is important because:

there is an opportunity to facilitate sharing of data and parts between cooperating groups to improve biomanufacturing efficiency

Our approach will be to:

- Build buy-in to the consortium by having a minimal demonstration of productivity using the reference collection
 - Design a minimally viable datasheet that demonstrates the utility of comparing bioprocesses
 - Consider analytic validation techniques (RNA-seq, metabolomics, etc.) and who would do the validation; Include all the stakeholders: metabolic engineering companies, toll fermenters, analytic manufacturers, academia at large
 - Establish a milestone timeline
-

Plans for next steps

The NIST SBSC team committed to producing this summary to be shared broadly to continue to solicit input from synthetic biology stakeholders. It was proposed that this summary report will be the basis for a more detailed white paper authored by the consortium to describe SBSC working group terms of reference as they develop over the next few months.

Next steps were discussed for establishing consortium operations and mechanisms for communication and sharing information. NIST will facilitate and support the individual working groups to develop their terms of reference and produce their standards. Moving forward there will be fluidity in working group membership and cross-participation in different working groups is encouraged. Consortium leadership will need to be established to drive progress and make decisions. This leadership will consist of working group leaders as well as steering committee and/or advisory board to guide SBSC decisions on a broader scale.

Communication and sharing mechanisms will be developed for the SBSC. These will include working group email lists, cloud drives, and/or web forums, etc. NIST will facilitate future meetings and interactions such as face-to-face workshops and conference calls. The SBSC website will be used to post and share information on SBSC activities, including this workshop report: <http://jimb.stanford.edu/sbsc>

We invite all interested parties to join the SBSC and welcome any additional feedback on this workshop report. We thank all workshop participants for their contributions. Lukmaan Bawazer, Ariel Hecht, Jeff Glasgow, Noah Spies, Jerod Parsons, and Peter McLean provided additional notes for this report and facilitation support.

Appendix A: Workshop Participants

Name	Organization	
Evan	Appleton	Boston University
David	Bachinsky	Molecular Creativity
Tom	Baer	Stanford University
Peter	Bajcsy	NIST Information Technology Laboratory
Maxwell	Bates	Autodesk
Lukmaan	Bawazer	NIST-JIMB
Jacob	Beal	Raytheon BBN Technologies
Aaron	Berliner	Autodesk Research
Swapnil	Bhatia	Boston University
Andrew	Bond	Gen9
Roel	Bovenberg	DSM
Patrick	Boyle	Ginkgo Bioworks
James	Brown	UK Synthetic Biology Leadership Council
Skyler	Brungardt	MachinaBio
Evren	Cakir	GenoFAB
Gisela	Canales	SGI-DNA
Will	Canine	Opentrons
Marcus	Carr	Riffyn, Inc.
Javier	Carrera	Stanford Bioengineering
Daniel	Chadash	Genome Compiler
Matthew	Chang	National University of Singapore
Chiu	Chau	OpenTrons
Erika	Check Hayden	Nature
Siyuan	Chen	Twist Bioscience
Mac	Cowell	Genefoo
John	Cumbers	SynBioBeta
Kim	de Mora	iGEM Foundation
Jed	Dean	Zymergen
Douglas	Densmore	Boston University
Connor	Dickie	Synbiota Inc.
Philip	Dormitzer	Novartis Influenza Vaccines

Omri	Drory	Genome Compiler
Bill	Efcavitch	Molecular Assemblies
Susan	Ehrlich	
Drew	Endy	Stanford & BioBricks
Steven	Evans	Dow AgroSciences
Micheal	Fero	TeselaGen Biotechnology
Paul	Freemont	Imperial College London
Emma	Frow	Arizona State University
Michal	Galdzicki	Arzeda Corp
Timothy	Gardner	Riffyn, Inc.
Jeff	Glasgow	NIST
Traci	Haddock	iGEM
Emily	Hatas	Pacific Biosciences
Ariel	Hecht	NIST
Matthew	Henry	Dow AgroSciences
Andrew	Hessel	Autodesk Inc
Nathan	Hillson	Joint BioEnergy Institute
Max	Hodak	Transcriptic
Jim	Hollenhorst	Agilent Technologies
Louise	Horsfall	University of Edinburgh
Karen	Ingram	Cut/Paste/Grow
Barbara	Jasny	Science/AAAS
Richard	Johnson	Global Helix LLC
Linda	Kahl	BioBricks Foundation
Richard	Kitney	Imperial College London
Fred	Kittler	Firelake
Eric	Klavins	University of Washington
Daniel	Kleinbaum	Emerald Therapeutics Inc
Tom	Knight	MIT
Todd	Kuiken	Woodrow Wilson Center
Steve	Laderman	Agilent Technologies, Inc
Dae Hyun	Lee	University of Washington
Sara	Lefort	Stanford University

Appendix A: Workshop Participants

Joshua	Lerman	Amyris
Kevin	LeShane	Lattice Automation
Cory	Li	OpenTrons
Sheng	Lin-Gibson	NIST
Laurie	Locascio	NIST
Aleksandra	Matyska	MIT
Matthew	Mattozzi	Wyss Institute, Harvard University
Joseph	McAuliffe	DuPont Industrial Biosciences
Peter	Mclean	NIST/Stanford
Amor	Menezes	University of California, Berkeley
Jeremy	Minshull	DNA2.0
Sarah	Munro	NIST-JIMB
Matt	Munson	NIST
Vivek	Mutalik	LBNL
Chris	Myers	University of Utah
Chris	Myers	University of Utah
Joel	Myerson	Agilent Technologies
Ernst	Oberortner	Joint Genome Institute (JGI) - Lawrence Berkeley National Labs (LBNL)
Kenneth	Oye	MIT
Megan	Palmer	Stanford
Vanya	Paralanov	NIST Materials Measurement Laboratory
Jerod	Parsons	NIST-JIMB
Morgan	Paull	Stanford Bioengineering
Matt	Percival	Riffyn, Inc.
Kashef	Qaadri	Biomatters
Carlo	Quinonez	MachinaBio
Randy	Rettberg	iGEM
Melissa	Rhoads	Lockheed Martin
Ingmar	Riedel-Kruse	Stanford University
Ryan	Ritterson	UCSF
Veronica	Rocha	Amyris and ASTM E62 (Liaison sub-committee)

Nicholas	Roehner	Boston University
David	Ross	NIST Materials Measurement Laboratory
Lexie	Ross	Center for International Security and Cooperation (CISAC)
Hans	Roubos	DSM
Marc	Salit	NIST-JIMB
Karl	Sanford	DuPont Industrial Biosciences
Mary	Satterfield	NIST
Herbert	Sauro	University of Washington
Leona	Scanlan	National Institute of Standards & Technology (NIST)
Markus	Schmidt	Biofaction
Dorothy	Silverman	Autodesk
William	So	FBI
Noah	Spies	NIST/Stanford
Ram	Sriram	NIST
Wesley	Straub	Twist Bioscience
Elizabeth	Strychalski	DARPA, NIST
Anu	Thubagere	Caltech
Thomas	Treynor	Zymergen, Inc.
Noël	van Peij	DSM
Lili	Wang	NIST
Sean	Ward	Synthace Ltd
Arnie	Wernick	Wernick & Associates
Dave	Whelan	Nancy J Kelley & Associates
Adison	Wong	National University of Singapore
Enoch	Yeung	Caltech
Wen Shan	Yew	National University of Singapore

Appendix B: NIST workshop framing slides

Synthetic Biology Standards Consortium Kick-off Workshop

Sponsored by the ABMS Affiliate Program

March 31, 2015

Sarah Munro, Matt Munson, & Marc Salit

Genome-Scale Measurements Group
JIMB – Joint Initiative for Metrology in Biology
Material Measurement Laboratory




Synthetic Biology Standards Consortium Kick-off Workshop

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Genome-Scale Measurements Group
JIMB – Joint Initiative for Metrology in Biology
Material Measurement Laboratory



Open, public meeting
@SynBioStandards, #bsc

NIST, setting the standards America lives by...

- U.S. Department of Commerce
- Advance measurement science, standards, and technology
- Non-regulatory
- Convening power



NIST, founded to meet national standards needs



National Bureau of Standards established by Congress in 1901

- Eight different “authoritative” values for the gallon
- Electrical industry needed standards
- American instruments sent abroad for calibration
- Consumer products and construction materials uneven in quality and unreliable

Article I, Section 8: The Congress shall have the power to...*fix the standard of weights and measures*

NBS became NIST in 1988

Appendix B: NIST workshop framing slides

**We all need standards
to put out fires or enable engineering feats**



Thousands of NIST Standards



Our team has built standards...

- Whole Human Genome Reference Materials
 - Genome in a Bottle Consortium (GIAB)
- Sequence library for RNA Spike-in Controls
 - External RNA Controls Consortium (ERCC)




External RNA Controls Consortium was initiated by industry to put out a fire...

5676-5684 Nucleic Acids Research, 2003, Vol. 31, No. 19
DOI: 10.1093/nar/gkg763

Evaluation of gene expression measurements from commercial microarray platforms

Paul K. Tan, Thomas J. Downey¹, Edward L. Spitznagel Jr², Pin Xu, Dadin Fu, Dimitar S. Dimitrov³, Richard A. Lempicki⁴, Bruce M. Raaka⁵ and Margaret C. Cam⁶

Microarray Core Laboratory, National Institute of Diabetes and Digestive and Kidney Disorders (NIDDK), National Institutes of Health, ¹Parick Incorporated, ²Department of Mathematics, Washington University, ³Laboratory of Experimental and Computational Biology (LECB), National Cancer Institute, NIH, ⁴National Institute of Allergy and Infectious Diseases (NIAID), NIH, ⁵SACF-Federick, Inc., ⁶Clinical Endocrinology Branch, NIDDK, NIH, USA



- Irreproducible gene expression measurements
- NIST hosted ERCC to develop solutions
 - RNA spike-in controls
 - Documentary standards
 - Software for standardized analysis

Appendix B: NIST workshop framing slides

ERCC: answering the call for reproducible gene expression results

What is the problem?	Irreproducible gene expression measurements across technology platforms
Who needs this problem solved?	Technology developers, clinical labs, government, academia, industry
What products will you develop together to solve the problem? What will success look like?	RNA spike-in controls, analysis software, and documentary standards used by everyone

GIAB: supporting the future of precision medicine

What is the problem?	So you've sequenced my genome, how well did you do?
Who needs this problem solved?	Regulators, clinical labs, technology developers, government, academia, industry
What products will you develop together to solve the problem? What will success look like?	Whole human genome reference materials, reference data, analysis methods, performance metrics, and documentary standards used by everyone

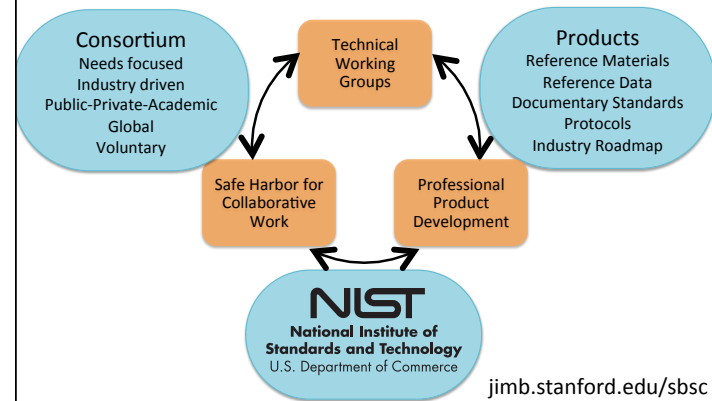
We work with our customers

- Whole Human Genome Reference Materials
 - Genome in a Bottle Consortium (GIAB)
- Sequence library for RNA Spike-in Controls
 - External RNA Controls Consortium (ERCC)



Synthetic Biology Standards Consortium

Setting the standards you can build on.



Appendix B: NIST workshop framing slides

LEAP
Laboratory for Emerging Applications in Process

A Vision for a Synthetic Biology Standards Consortium

Sarah Moore, National Institute of Standards and Technology, sarah.moore@nist.gov
Patrick Swick, Google BioWorks, patrick@googlebioworks.com
Jeff Uffner, Amerys, jeffuffner@gmail.com

Synthetic Biology LEAP Strategic Action Plan
Version 2: March 18, 2013*

Synopsis
The promise of synthetic biology to be instrumental in improving global quality of life and economic security can not be realized if there is not a concerted effort to transform synthetic biology innovations into useful, safe, and affordable products. As synthetic biology continues to develop, growing numbers of government and non-government organizations have focused on how synthetic biology could be used to responsibly improve global quality of life while considering environmental and health safety issues. The development of measurement, performance, and safety standards for synthetic biology by a multi-stakeholder consortium could be the most effective way of ensuring the responsible development and wide acceptance of this technology.

I. Strategic vision
The synthetic biology community has grown to a critical mass of industry, academic, and government members and a consortium of these partners dedicated to developing measurement standards for the field could have high impact. Effective development of any new technology requires accurate measurement standards to assess product and process performance, reliability, and safety. A consortium could unify the shared interest of the public and the synthetic biology community for development of standards that enable the responsible application of the technology to serve the public good. These standards could facilitate communication by providing a shared language for discussions about product and technology performance across institutional and disciplinary boundaries. They could also reduce the barrier to entry and increase the rate of innovation of product development using synthetic biology by providing a shared community resource open to all. It is likely that some of these standards already exist in the field and are not shared and must be redeveloped by each new entrant into the synthetic biology field. By providing the field with a shared language of measurements and standards, a consortium could foster responsible innovation in the field.

*This paper is a working version. Please contact the authors to provide feedback for the most recent version of the strategic action plan. See <http://www.leap-nist.org>

Today's plan

- Workshop framing
- Working group pitches and discussion
- Working group narrative-building
- Working group stories
- Plans for next steps

Break at 10:30 am
Lunch at 12:30 pm
Break at 2:30 pm
Adjourn at 4:30 pm

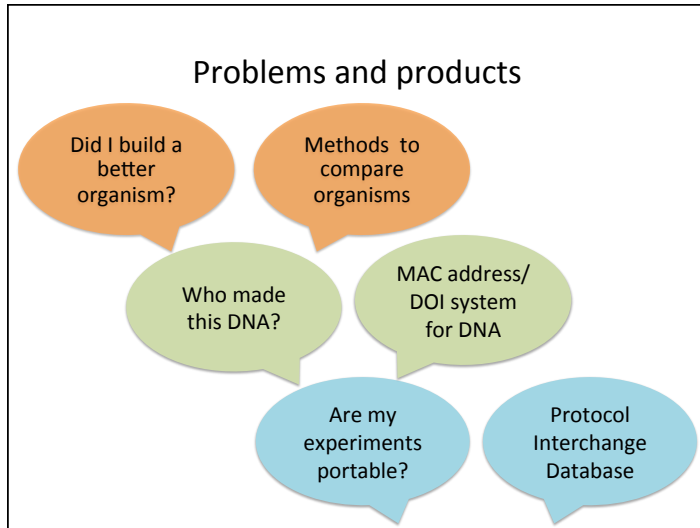
Dynamic array of Working Groups

Automation and Protocol Interoperability	DNA Construction
Digital Biological Information	DNA Watermarking
Measurements for Regulated Applications	Performance Metrics for Engineered Strains
Flow Cytometry	Others, as they arise

- Each working group to develop story, success measures
- Consortium as host
 - Standards-setting environment
 - Safe harbor
- Ad hoc governance
- Volunteer-driven
 - NIST-hosted

Candidate Working Groups

Automation and Protocol Interoperability	Minimal information standards	DNA Construction	Metrics beyond cost per base
Digital Biological Information	Describe genetic function and context	DNA Watermarking	Authentication and identification standards
Measurements for Regulated Applications	Guidance documents, best practices	Performance Metrics for Engineered Strains	Systematic approaches for strain comparison
Flow Cytometry	Calibration standards and protocols	Others, as they arise	Your thoughts here...



Working groups should answer these questions

What problem will this working group solve?

Who needs this problem solved?

What products will you develop together to solve the problem? What will success look like?

- ### How we operate
- You get out of it what you put into it
 - NIST-hosted
 - *not funded*
 - Technology agnostic
 - Decision-making
 - Consensus-based
 - Data-driven
 - Leadership group as a steering body

- ### How we operate
- You get out of it what you put into it
 - NIST-hosted
 - *not funded*
 - Technology agnostic
 - Decision-making
 - Consensus-based
 - Data-driven
 - Leadership group as a steering body
- "No proprietary information will be shared at the workshop."
FRN #2015-06839 (SBSC is a pre-competitive space)*
- Our intention is that SBSC standards are free to practice.*

Charge to the Workshop

- Establish working groups (WGs)
 - Answers to “3 Questions”
 - WG terms of reference
 - WG leadership, structure, and operation
- Identify initial portfolio of work
 - We hope to get 2-3 concrete projects with 12-18 month deliverables

Working Group Terms of Reference

This is a sentence that describes what our working group will try to accomplish

This is a sentence that describes why it is important

These are our working groups specific approaches

- *This is a bulleted describing the specifics of how this will get done*
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