Thank you for inviting public input on the ICCVAM Strategic Roadmap for a National Strategy on new approaches for evaluating safety of chemicals and medical products. It is an exciting time to be in science. A time when our highest scientific and ethical potentials hold promise to not only meet, but to run a course together.   I want to share an idea called GIVVISH (Global In Vitro Validation In Silico Human).

GIVVISH is a proposed, collaborative, non-profit public service project that aims to design, develop, deploy, and maintain a socially-scaled human-relevant method validation platform and library. It can support a National Strategy, as well as a Global one. It will function in real-time and utilize the power of "Big Data" and end-user collaboration to achieve a predictive, human-relevant model in 3-7 years, replacing the animal model with a new Gold Standard that fits the 21st century.   I realize that's a lot faster that what is usually discussed, but timelines are often a function of how many people are involved on a project and GIVVSH involves everyone in the solution.   Everyone is a collaborator.

- Platform will feature user/enterprise level security and sharing settings.
- Authenticated Individual researchers, groups, and/or companies will be able to register a profile to utilize the platform to create a new project, open an existing project, and/or compete on a project.
- Users may register/open an endpoint, biomarker, therapeutic candidate, compound, drug entity, target organ, disease condition, or device for viewing data, uploading data, and extracting data for predictive modeling.
- Platform will incorporate intuitive design and state-of-the-art machine learning capabilities to analyze data in real-time for statistically significant modeling that continually updates and refreshes code and data sets.
- Hadoop/ and adjunctive software; configuration will be optimized and accept a wide variety of end-user and enterprise data formats for straight-forward, minimal-programming interface for upload of both historical and newly-generated data.   An Advisory Board will liaise and oversee platform data requirements.
- Platform will produce data sets, charts, graphs and other visual representations of data at all levels of input and analysis and include social feature with peer review, interpretation, and feedback, based on user sharing/security settings.
- Data will conform to electronic records regulatory and GLP requirements as applicable.
- Platform design will incorporate machine-learning and critical analysis tools for continuous optimization.
- Regulatory agency is final arbiter of validation approvals.
- All shared data and projects in Data Lake will be available to platform users for query for conducting studies, from hypothesis testing, Method Comparability, Method Performance, ect.
- Existing validated methods as well as platform-generated validated methods will be available on platform library for query.

The 21st Century way of doing things: Social. Connected. Cutting-edge IT. Peer to peer. End-user empowered. Bottom-up Collaboration. These things have become essential to innovation today and are especially important for achieving a predictive model. Why?   Because a century's worth of status quo is a big hurdle to clear. We have become dependent on animals for studying the effects of chemicals and drugs for a very long time. We've presumed a correlation, based on a shared experience among species- emotion, pain, and suffering. Our innate intelligence is always looking for a fuller story,

a bigger picture. There is so much to learn when data speaks to each other. And people work together. We have everything we need to do this now-   To catapult health and medicine into its rightful place in the 21st century.

The GIVVISH project is interested in building our Founding Board of Advisors to advance the platform design to the next level.   The expertise of everyone working on this important topic is needed and appreciated.   The GIVVISH vision is a human-predictive model that will help deliver safer, more efficacious therapies, spur innovation, reduce cost, and align with our highest scientific and ethical potential. For a detailed overview of the GIVVISH project, please visit our website at GIVVISH.org

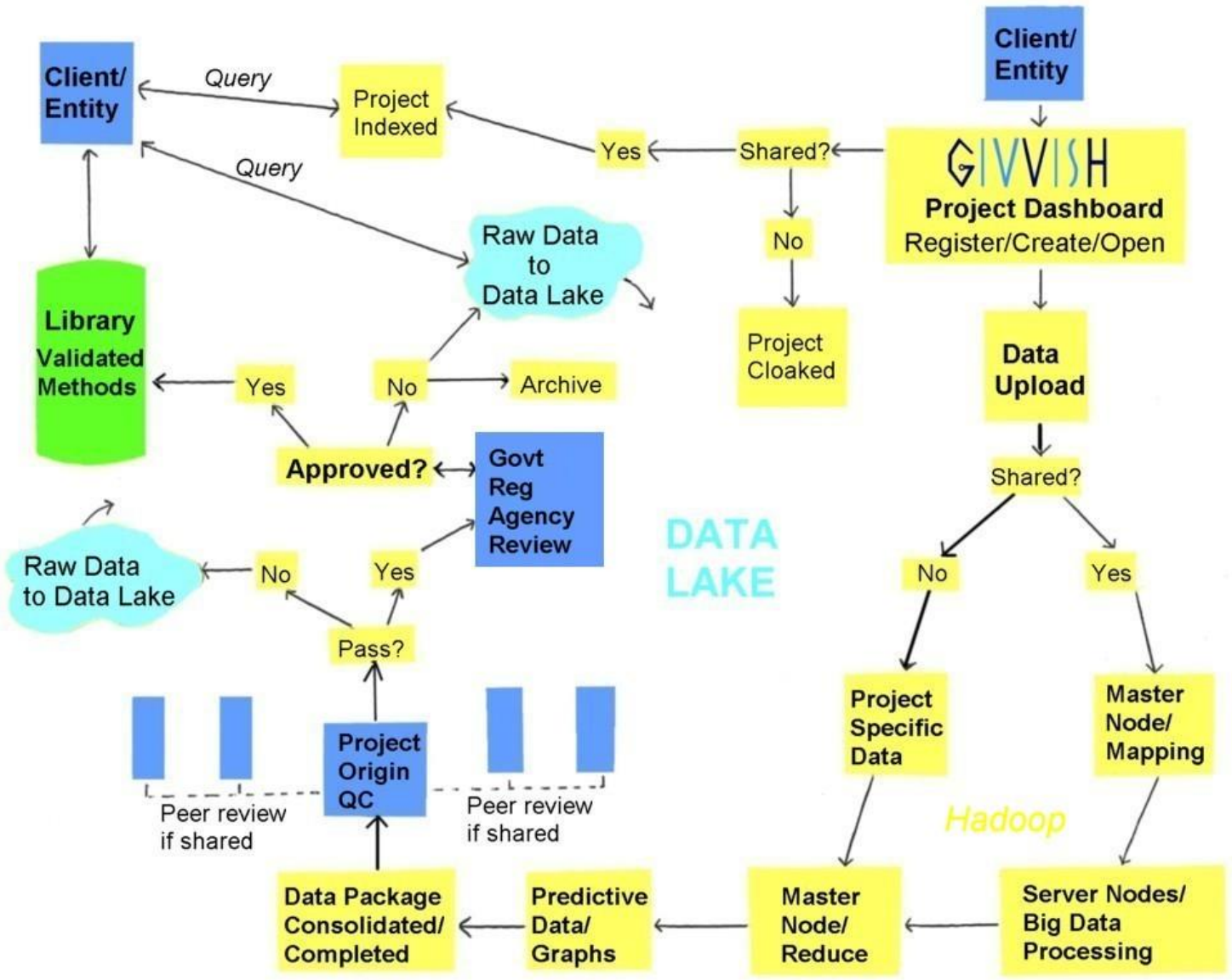Thank you.

Sincerely,

Christine Rowen

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GIVVISH

GLOBAL IN VITRO VALIDATION IN SILICO HUMAN

STREAMLINING HUMAN RELEVANT METHOD VALIDATION-
A 21st CENTURY COLLABORATION PLATFORM

DATA INPUT ORIGINS:

- INDUSTRY
- GOVERNMENT
- ACADEMIA
- DEVICE MAKERS
- CONSORTIA
- EXISTING DATABASES
- CLINICAL TRIALS
- HISTORICAL DATA
- POST-MARKET DATA

DATA OUTPUTS:

- CALCULATIONS
- PROBABILITY PLOTS
- DIAGNOSTICS (R, R-sq, p-value, BIC, AIC)
- CORRGRAMS
- ANOVA
- SUMMARY

Streamling Validation of Human Relevant Methods utilizing "Big Data"
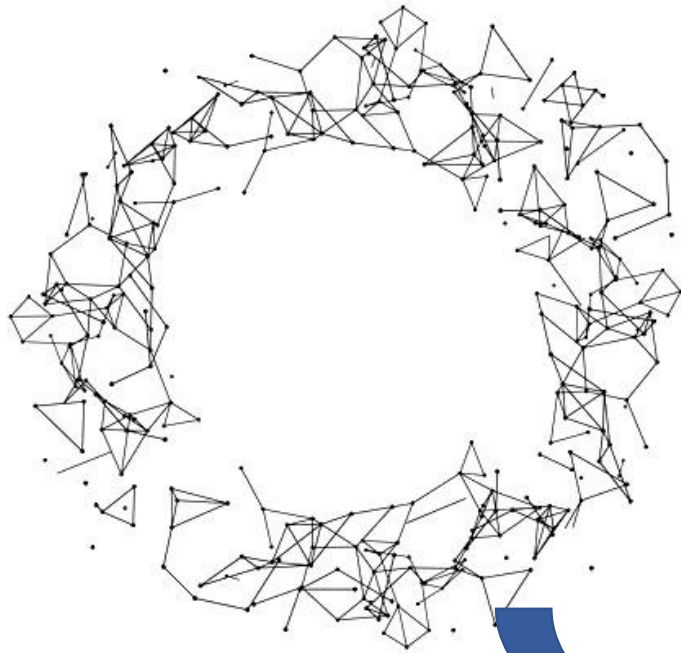
KEY FEATURES

- BOTTOM-UP BUILD
- BIG DATA with REALTIME PROCESSING
- SOCIALIZES THE DATA, THE HUMAN RELEVANT CHALLENGE & THE SOLUTION
- USER-LEVEL (ENTERPRISE LEVEL) SECURITY/SHARING
- COLLABORATIVE
- PEER REVIEW
- CENTRALIZES LIBRARY OF EXISTING VALIDATED METHODS
- ORGANIC VALIDATION MECHANISM
- ORGANIZES DATA/MERGES NEW DATA
- SUPPORTS EDUCATION/ NATURAL LEARNING CURVE
- SUPPORTS REGULATORY DECISION BURDENS
- FEEDBACK MECHANISM TO ALL STAKEHOLDERS
- CENTRALIZES COMMUNICATION
- INFINTE DATA SEARCH CAPABILITIES
- RESEARCH TOOL

The User is a Collaborator

- ✓ Search and View shared data and projects
- ✓ Open and Create New projects and upload data
- ✓ Research, Compute, and Extrapolate data and reports
- ✓ Create and Perform Optimization Studies
- ✓ Perform Hypothesis Testing
- ✓ Create Statistical Reports against any searchable criteria
- ✓ Assess Method Performance against any searchable criteria
- ✓ Peer Review projects and provide feedback
- ✓ Communicate with other platform users
- ✓ Perform Trend Analysis on Validated Methods Life Cycle
- ✓ Conduct Method Comparability Studies
- ✓ Provide feedback on DOE (Design of Experiments)

GIVVISH

- ✓ DISCOVER
- ✓ OBSERVE
- ✓ CORRELATE
- ✓ CONFIRM

GIVVISH

SHARING

GIVVISH

GLOBAL IN VITRO VALIDATION IN SILICO HUMAN

Thank You!

Contact:
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