

November 16-17, 2022  
Hosted by Ionis Pharmaceuticals  
Carlsbad, CA  
*By invitation only*

PRISME Forum  
Fall 2022  
Technical Meeting

# Modernization of the Laboratory Ecosystem

# Modernization of the Laboratory Ecosystem

Technology breeds technology and ever enhancing technology sophistication informs and enables scientific method. Pharmaceutical industry research scientists have a plethora of tools ranging from those that support the well-understood small molecules through the increasingly important biological drugs such as oligonucleotide, drug antibody conjugates into the increasingly exciting and impactful cell and gene therapies. Indeed, digital therapeutics are starting to make an impact in the pharmacopoeia.

Research scientists understand the need for improved R&D IT capabilities to support these new research modalities but what should the improved capabilities look like?

## PRISME Forum Fall 2022 Technical Meeting Advisory Committee

Christian Baber	Head of Scientific & Pharmaceutical Data, IS	Johnson & Johnson
Sonia Banerjee	Global Business Domain Architect for R&D and PDM	Gilead Sciences
<b>Alastair Binnie*</b>	<b>Technical Meeting Co-Chair</b>	<b>PRISME Forum</b>
Robin Brouwer	IT lead for global labs, early science	AstraZeneca
Dan Chapman	Head of IT New Medicines Information Management	UCB
Sasker Grootjans	New Medicines IT Sr. Project Manager	UCB
Hongmei Huang	Vice President, Development Sciences Informatics	Genentech
Christina Lu	Executive Director	Genentech
<b>Michael Montello*</b>	<b>Senior Vice President, R&amp;D Technology; Technical Meeting Co-Chair</b>	<b>GSK</b>
Leah O'Brien	Senior Product Director, Development Lab Systems	GSK
David Sedlock	Operations Team	PRISME Forum
Etzard Stolte	VP & Global Head Knowledge Management	Roche
John Wise	Operations Team	PRISME Forum

# PRISME Forum Fall 2022 Technical Meeting

## Modernization of the Laboratory Ecosystem

### PROGRAM







All sessions will be held at Ionis Pharmaceuticals, 2855 Gazelle Ct, Carlsbad, CA 92010 unless otherwise noted.

WEDNESDAY, November 16, 2022		
18:20	Gather in the Cassara Carlsbad Hotel for PRISME Forum Group Reception	
18:30	<b>Fireside Chat at the Cassara Carlsbad with</b> <a href="#">Jay Rughani</a> , Investment Partner, <i>Andreessen Horowitz</i> and <a href="#">Sajith Wickramasekara</a> , CEO, <i>Benchling</i>	
THURSDAY, November 17, 2022		
07:30	Gather in the Cassara Carlsbad Hotel for departure to the meeting venue ( <b>please have picture ID</b> )	
08:15	Check-in, continental breakfast, and showcase setup	
08:45	Welcome Notes & Introductions	<a href="#">Dan Chapman</a> , Chair, <i>PRISME Forum</i> <a href="#">Alastair Binnie</a> , Technical Meeting Chair, <i>PRISME Forum</i>
<b>SESSION I</b> Keynote		Chair: <a href="#">Alastair Binnie</a> , Technical Meeting Chair, <i>PRISME Forum</i>
09:00	Data capture automation: the 100 meters hurdles	<a href="#">Alice Laures</a> , Director, Product Owner for CMC Digital Data and Analytics, <i>GSK</i>
<b>SESSION II</b> Big Tech – Lightning Talks		Chair: <a href="#">Christina Lu</a> , Executive Director, <i>Genentech</i>
9:35	Introduction	<a href="#">Christina Lu</a> , Executive Director, <i>Genentech</i>
9:45	Google - building labs of the future with the Cloud	<a href="#">Riju Khetarpal</a> , Director, Global Healthcare & Life Sciences Partnerships @GoogleCloud
10:10	AWS - creating connected labs that scale	<a href="#">Lee Tessler</a> , Life Sciences, Worldwide Technology Leader, <i>Amazon</i>
10:35	Coffee Break	
11:05	Microsoft - modelling and lab automation to optimize ex-vivo organoids for precision cancer medicine	<a href="#">Ava Amini</a> , Senior Researcher, <i>Microsoft</i>
11:30	Accenture: three key steps towards the modern laboratory ecosystem: foundation, transformation and aspiration	<a href="#">Mark Fish</a> , Managing Director, <i>Accenture</i>
<b>SESSION III A</b> Showcase		Chair: <a href="#">Sonia Banerjee</a> , Global Business Domain Architect for R&D and PDM, <i>Gilead</i>
11:55	Showcase (three 15-minute rotations – before lunch and three 15-minute rotations after lunch)	
11:55	Introduction	<a href="#">Sonia Banerjee</a> , Global Business Domain Architect for R&D and PDM, <i>Gilead</i>
S1	Q <sup>2</sup> Solutions - data automation in the central lab	<a href="#">Mike Hamill</a> , VP, IT, <i>Q<sup>2</sup> Solutions</i> <a href="#">Jian Wang</a> , VP, Head of Digital Innovation, <i>Q<sup>2</sup> Solutions</i>
S2	CellPort Software	<a href="#">Patrick Dentinger</a> , CEO, <i>CellPort Software</i>
S3	Optimizing sponsor <> CRO laboratory data transfer	<a href="#">Claus Stie Kallesøe</a> , Founder/CEO, <i>grit42</i>
S4	Emerald Cloud Labs - transferring and automating (virtually) workflows for a formulation group.	<a href="#">Malav Desai</a> , Sci. Ed. Engineer, <i>Emerald Cloud Lab</i> <a href="#">Toby Blackburn</a> , Business Development, <i>Emerald Cloud Lab</i>
S5	Strateos	<a href="#">Mark Fischer Colbrie</a> , President, CEO, <i>Strateos</i>
S6	Delivering digital solutions that improve lab efficiency and enhance lab life	<a href="#">Bill Goodman</a> , Sr. Director of Product Management - Digital Science at <i>Thermo Fisher</i>
12:45	Lunch	

	<b>SESSION III B Showcase</b>	Chair: <a href="#">Sonia Banerjee</a> , Global Business Domain Architect for R&D and PDM, <i>Gilead</i>
<b>13:45</b>	<i>Showcase Session Continues (remaining three 15-minute rotations)</i>	
	<b>SESSION IV Presentations</b>	Chair: <a href="#">Leah O'Brien</a> , Senior Product Director, Development Lab Systems, <i>GSK</i>
<b>14:30</b>	<b>The future of the laboratory ecosystem: some perspectives from pRED</b>	<a href="#">Pedro Ivo Guimaraes</a> , Senior Scientist and Product Manager, <i>Roche</i>
<b>15:00</b>	<b>The central role of scientific ontology in laboratory assay data harmonization</b>	<a href="#">Xiangdong (Sean) Liu</a> , Global Head, Scientific Assets & Decision Support, <i>Takeda</i>
<b>15:30</b>	<i>Break</i>	
	<b>SESSION V Panel Discussion</b>	Chair: <a href="#">Alastair Binnie</a> , Technical Meeting Chair, <i>PRISME Forum</i>
<b>15:45</b>	<b>Panel Discussion</b>	<p>Session chairs from the day:</p> <ul style="list-style-type: none"> <li>• Session II: <a href="#">Christina Lu</a>, <i>Genentech</i></li> <li>• Session III: <a href="#">Sonia Banerjee</a>, <i>Gilead</i></li> <li>• Session IV: <a href="#">Leah O'Brien</a>, <i>GSK</i></li> <li>• <a href="#">Dan Chapman</a>, <i>UCB</i></li> </ul>
	<b>SESSION VI Meeting Summary, Awards</b>	Chair: <a href="#">Alastair Binnie</a> , Technical Meeting Chair, <i>PRISME Forum</i>
<b>16:30</b>	Meeting Summary and Spring 2023; Awards	
<b>16:45</b>	Networking Reception	
<b>18:00</b>	<i>Return to the hotel</i>	
<b>18:30</b>	<i>Group dinner</i>	

## Short biography legend:

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-  Meeting co-chair
  -  Technical Meeting Advisory Committee member
  -  Session chair
  -  Podium Presenter
  -  Showcase Presenter
  -  Fireside Chat Panelist
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## Ava Amini, PhD

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[Ava Amini](#) is a Senior Researcher in the Biomedical Machine Learning group at Microsoft Research, New England. Her research focuses on developing new computational technologies for precision medicine, where she works at the interface of machine learning, cancer biology, and bioengineering.

She completed her PhD in Biophysics at Harvard University and her SB in Computer Science and Biology at MIT. In addition to research, she is passionate about machine learning outreach and leadership: she served as a lead organizer and instructor for MIT Introduction to Deep Learning and is a co-founder of Momentum AI, which provides

all-expenses-paid programs for high schoolers to learn AI.

### Microsoft - modelling and lab automation to optimize ex-vivo organoids for precision cancer medicine

Designing next-generation precision therapies requires the ability to faithfully model an individual's biology in the lab. Ex vivo organoids, 3D cultures of cells grown from patient-derived tissue, are a transformative advance in the state of the art of experimental model systems. Organoids meet many of the open needs in precision medicine: they can retain key aspects of disease biology, be profiled over time, and be used to screen candidate treatments. However, achieving their clinical translation requires optimizing organoid platforms across tissue types and patient profiles.

This talk will share how Microsoft Research, together with our experimental and clinical collaborators, is developing new solutions to this challenge by unleashing the power of computation, big data, and machine learning. We present our recent work in building an integrated analytic framework for pancreatic cancer organoids and conclude by sharing how we are scaling this approach with the ultimate aim of discovering effective new precision therapies.

## Christian Baber, PhD

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[Christian Baber](#) is a chemist by training and holds undergraduate and PhD degrees in computational chemistry with a focus on AI techniques to assess the synthetic accessibility of de novo design compounds.

Christian continued this work with a post-doctoral fellowship on the automated design of targeted combinatorial libraries at the Department of Knowledge Engineering, Osaka University, Japan before moving into industry initially as a computational chemist and cheminformatician.

Christian has a wide breadth of R&D experience across companies ranging from startups to large pharma and diverse therapeutic areas with a focus on informatics and predictive modeling for drug discovery but has also managed lab and automation teams including compound management and high-throughput purification.

After spending the previous 6 years leading Scientific Computing & Informatics and R&D IT at Shire Takeda, Christian moved to Janssen (J&J) in 2021 where he now leads the global Scientific & Pharmaceutical Data, Informatics and Systems function in R&D.

In addition to his day job, Christian sits on a number of scientific & industry advisory boards and is a Director of both the Pharmaceutical R&D Information Systems Management Executive (PRISME) Forum and Pistoia Alliance.

## Sonia Banerjee, MS



[Sonia Banerjee](#) is a Senior Director in Gilead Sciences responsible for Portfolio Architecture and Quality Systems in their Research to Release IT. In her role she is responsible for developing the Next Generation Data and Digital strategy and Roadmaps for the Research, Development, Manufacturing's and Supply Chain functions.

Over her 25 year career Sonia has held multiple leaderships roles, enabling business capabilities for Biopharmaceutical and High Tech Industries. Sonia has also been active across the industry, leading workgroups at industry forums such as Parenteral Drug Association (PDA) and BioPhorum contributing to industry standards.

Sonia holds a Bachelor's Degree in Mathematics and Graduate Diploma in Systems Management. She is PMP and Sigma Black belt certified and also holds certifications from MIT Sloan School of Management and Rutgers in Emerging Technologies (Big Data, IoT, ML, AI) for Business.

## Alastair Binnie



[Alastair Binnie](#) retired in 2022 as Head of Information Technology for Research & Development at Bristol-Myers Squibb. In this role he was accountable for planning and delivering all aspects of IT's value proposition to BMS R&D, which included digital platforms supporting discovery, preclinical, translational medicine, clinical development, regulatory sciences, pharmacovigilance, and medical affairs. His mission was to enable R&D by providing the right tools and the right data, to the right scientists, at the right time. He joined BMS in 1999 as the leader of the Discovery Automation team in Wallingford, Connecticut, and progressed through a range of leadership roles in research technology and IT.

From 1994-99 he led the Discovery Technologies group at Glaxo Wellcome R&D in the UK. Prior to joining the pharmaceutical industry, Alastair worked as a design engineer in the space industry, developing instrumentation for microgravity research for the European Space Agency. He is a current or recent Board member of global life-science technology industry groups, including PRISME, the Society of Laboratory Automation and Screening, and the Pistoia Innovation Alliance. He represented BMS on the New Jersey Technology Council.

Alastair grew up in Scotland. He has degrees in mechanical engineering, design engineering and industrial design from Brunel University, Imperial College of Science and Technology, and the Royal College of Art.

# Toby Blackburn, MBA



[Toby Blackburn](#) serves as the head of Business Development and Strategy at Emerald Cloud Lab (ECL), a web-based platform for remotely conducting and managing data surrounding wet lab experiments.

Prior to Emerald, Toby worked at Biogen in a number of roles across CMC, R&D and Medical Affairs.

He holds an MBA from Duke University's Fuqua School of Business, and a BS in Chemical Engineering from North Carolina State University.

*Toby will co-present with Brian Frezza on the Emerald Cloud Labs - transferring and automating (virtually) workflows for a formulation group.*

## Emerald cloud labs - transferring and automating (virtually) workflows for a formulation group

# Robin Brouwer, MS



Robin Brouwer joined AstraZeneca 18 years ago working in IT across R&D including late stage development areas Clinical and Regulatory, and the past 8 years within Early Science. Robin has held various positions including developer, architect, project manager and now BRM & Digital Lab IT lead including R&D labs globally. In this position, Robin is accountable for developing IT capability roadmaps in partnership with early science stakeholders, developing business cases for major investments, monitoring progress of in-flight projects.

The Digital Lab investment targets improving laboratory efficiency as priority area and Robin is leading the capability that aims to release significant time back to science driven by optimizing experimental workflows, deploying automation and ensuring that scientists are fully equipped and supported in laboratories.

# Atul Butte, MD, PhD



[Dr. Atul Butte](#) is the Priscilla Chan and Mark Zuckerberg Distinguished Professor and inaugural Director of the Bakar Computational Health Sciences Institute (bchsi.ucsf.edu) at the University of California, San Francisco (UCSF). Dr. Butte is also the Chief Data Scientist for the entire University of California Health System, the tenth largest by revenue in the United States, with 20 health professional schools, 6 medical schools, 6 academic health centers, 10 hospitals, and over 1000 care delivery sites.

Dr. Butte has been continually funded by NIH for 20 years, is an inventor on 24 patents, and has authored nearly 300 publications, with research repeatedly featured in the New York Times, Wall Street Journal, and Wired Magazine.

Dr. Butte was elected into the National Academy of Medicine in 2015, and in 2013, he was recognized by the Obama Administration as a White House Champion of Change in Open Science for promoting science through publicly available data. Dr. Butte is also a co-founder of three investor-backed data-driven companies: Personalis (IPO, 2019), providing medical genome sequencing services, Carmenta (acquired by Progenity,

2015), discovering diagnostics for pregnancy complications, and NuMedii, finding new uses for drugs through open molecular data.

Dr. Butte trained in Computer Science at Brown University, worked as a software engineer at Apple and Microsoft, received his MD at Brown University, trained in Pediatrics and Pediatric Endocrinology at Children's Hospital Boston, then received his PhD from Harvard Medical School and MIT.

## Translating a trillion points of data into therapies, diagnostics, and new insights into disease

There is an urgent need to take what we have learned in our new data-driven era of medicine, and use it to create a new system of precision medicine, delivering the best, safest, cost-effective preventative or therapeutic intervention at the right time, for the right patients. Dr. Butte's teams at the University of California build and apply tools that convert trillions of points of molecular, clinical, and epidemiological data -- measured by researchers and clinicians over the past decade and now commonly termed "big data" -- into diagnostics, therapeutics, and new insights into disease.

Dr. Butte, a computer scientist and pediatrician, will highlight his center's recent work on integrating electronic health records data from over 8 million patients across the entire University of California, and how analytics on this "real world data" can lead to new evidence for drug efficacy, new savings from better medication choices, and new methods to teach intelligence – real and artificial – to more precisely practice medicine.

## Dan Chapman, PhD



[Dan Chapman](#) is part of the leadership team within Informatics at UCB with responsibility for Software Development and Architecture and Therapeutic Informatics (UK). Dr. Chapman has 15 years' experience working within the pharmaceutical industry in a variety of roles.

After completing a PhD in Chemistry at Warwick University, he transitioned to informatics during post-doctoral research at Cambridge University as part of the CLIC consortium. Dr. Chapman joined AstraZeneca in 1997 and worked on a variety of global projects before joining UCB in his present role in 2005.

Since then, he has driven several projects to revolutionize the informatics platform within UCB and is currently actively involved in promoting Data Science across UCB.

## Patrick Dentinger



[Patrick Dentinger](#) is CEO and founder of CellPort Software, a company he spun off from Absorption Systems, which he co-founded and where he was CEO for twenty years until its sale in November 2020 to Pharmaron. During this tenure, Absorption Systems transformed from a preclinical Contract Research Organization to a world leader in GMP analytical testing for Cell & Gene Therapies. From its inception through today, Absorption Systems operates as an analytical CRO dedicated to the continued development of test systems to accurately predict human outcomes. Initially focused on in vitro models to predict human pharmacokinetics, the company expanded its in-depth knowledge of cell-based and in vivo-based systems to characterize large molecules, biologics, drug delivery systems, gene therapies, cell therapies, and medical devices for both kinetics and efficacy.

Mr. Dentinger is a graduate of the University of California, Santa Barbara.



Under his leadership, Absorption Systems became a world leader in in vitro testing for non-clinical bioequivalence testing (Biopharmaceutical Classification System), in vitro release testing, and in vitro potency testing for cell and gene therapies. At Absorption Systems, it became Mr. Dentinger's vision to do away with paper lab notebooks and digitalize cell manufacturing. Realizing that no commercial software for managing cell culture existed, he created an in-house system—CellPort—to achieve his vision. Hearing positive feedback from the FDA and clients who had seen the software, Mr. Dentinger realized there was market potential for a software product focused on cell culture and its upstream and downstream data and processes. To commercialize the product, it was rebuilt from the ground up as a SaaS offering and spun off from Absorption Systems during the latter's acquisition by Pharmaron.

## Mark Fish



[Mark Fish](#) is a Managing Director in Accenture's Scientific Informatics Services Business. He has over 20 years of experience in leadership roles in Accenture, Brooks Life Sciences and Thermo Fisher Scientific delivering innovative solutions to the pharmaceutical sector and is passionate about drug discovery and development, translation research and precision medicine, digital transformation, agile software development and automation for analytical quality control, compound management and high throughput screening.

### Accenture – three key steps towards the modern laboratory Ecosystem: foundation, transformation and aspiration

Accenture research clearly shows a business imperative for more agile approaches to laboratory transformation. The transformation journey for laboratories starts with Foundational, Transformation and Aspirational steps. Doing the basics beautifully today requires new foundational thinking, building scientific capabilities in the cloud, with a platform strategy to address legacy systems.

Transforming to data driven ways of working requires the seamless flow of data and interoperability between "wet lab" and "dry lab" workflows. Organizations aspire to a future where the workforce is enabled by a workplace that bridges the digital and physical domains, automates menial activity, and superpowers science with applied intelligence. We will share our learnings to facilitate such steps.

## Mark Fischer Colbrie, MBA



[Mark Fisher Colbrie](#) is the CEO of Strateos, Inc. and has more than 30 years of experience in building laboratory tools, diagnostic, therapeutic and medical device companies. Strateos is a software technology and automation company that accelerates life science research by enabling cloud access to its broad scale automation. Previously, Mark was the CEO for over ten years at Labcyte Inc., which invented novel lab tools and automation that have been adopted world-wide. Before Labcyte, he ran business development and was the CFO at Adeza Biomedical Corporation, a women's healthcare company. He holds four issued patents for diagnostics and therapeutics. In 2013, Mark was named Ernst & Young Entrepreneur of the Year, Life Sciences for Northern California.

Mark is the former Chairman of the Board for JDRF International, the largest global funder seeking a cure for type one diabetes. As a 21 year JDRF volunteer, he served on the JDRF International Board for 7 years and was a member of multiple committees including Research, Finance and Nominating & Governance. For the Greater Bay Area JDRF Chapter, Mark served as the Chapter President for 3 terms and has been a board member for 18 years.

Mark holds a BA from Stanford University and an MBA from University of California, Berkeley. He has served on a life sciences industry board, the Analytical, Life Sciences Diagnostics Association (ALDA), since 2011.

## Malav Desai, PhD



[Malav Desai](#) is a bioengineer with experience in recombinant protein engineering, biomaterial development and phage display. His work has focused on the development of hydrogel materials with unique characteristics such as rubber-like flexibility, self-healing, wet adhesion and light-responsive actuation, and the use of phage for directed evolution and liquid crystal assembly, all with a focus on biomedical applications.

Throughout his work, he has gained experience for a broad range of analytical techniques and instruments used in synthetic biology, chemical and mechanical characterization of polymers/materials from nano- to macro-scales, and biosafety characterization of materials. Malav has a passion for using coding and scripting languages to analyze data, for prototyping experimental setups, and for developing electronic hardware and control software to effectively tackle the challenges he comes across.

Malav has a PhD in bioengineering and biomedical engineering from the University of California at Berkeley.

*Malav will co-present with Toby Blackburn on the Emerald Cloud Labs - transferring and automating (virtually) workflows for a formulation group.*

## Bill Goodman



[Bill Goodman](#) is the Senior Director of Product Manager for Digital Science Solutions at Thermo Fisher Scientific.

In his current role, he is responsible for leading the product management efforts for Thermo Fisher Scientific's Connect Platform.

With over 20 years of experience with software, informatics, and previous positions that focused on platform technology, Bill has career experience with cutting-edge technology and innovation.

## Delivering digital solutions that improve lab efficiency and enhance lab life

Does the digital lab solve scientists' problems? Is automation the key to advancement? The real route to progress is in making small changes that have a significant impact.

In this talk we will discuss Thermo Fisher Scientific's three rules to make lab life easier using digital solutions that are accessible today:

- Protect IP while making data more accessible
- Reserve instrument time, monitor experiments and analyze data
- Empower scientists to manage resources

## Sasker Grootjans, PhD



[Sasker Grootjans](#) is a senior IT project manager at UCB, for UCB's early research department. Since 2016, his project teams develop or deploy innovative solutions covering machine learning, virtual reality, ADMET modeling, statistics, and imaging. At UCB, Sasker is leading innovation efforts particularly around microscopy, imaging and virtual reality.

Sasker brings 11 years of experience in various research environments (wet and dry lab) and biotechnology development to UCB's IT department.

Prior to UCB, he did molecular signal transduction research at VIB and UGhent (Belgium), the Spanish National Center for Oncological Research (CNIO, Spain) and the KULeuven (Belgium).

Sasker received his PhD in Biotechnology from VIB/UGhent.

## Hongmei Huang, PhD, MS



As the Vice President of Development Sciences Informatics at Roche Genentech, [Hongmei Huang](#) is responsible for the strategic leadership around data management, informatics systems and analytics platforms for translational research and development functions. She is among the key leaders driving the Roche wide effort to make our data Findable, Accessible, Interoperable and Reusable (FAIR).

By connecting science and technology, Hongmei leads organizational drives to transform the data and informatics landscape for the advancement of medicines and healthcare. She is an accomplished scientific and informatics leader with over 25 years of experience in the Pharmaceutical Industry. She started her career as a Research Investigator at Bristol-Myers Squibb and transitioned into Informatics over the course of her career, with leadership roles in various companies including Novartis and Johnson & Johnson.

She received her BS from Beijing University, MS from University of Michigan, and PhD in BioOrganic Chemistry from The Scripps Research Institute.

## Pedro Ivo Guimarães



[Pedro Ivo Guimaraes](#) is Senior Scientist and Product Manager at Roche.

**The future of the laboratory ecosystem: some perspectives from pRED**

# Mike Hamill



[Mike Hamill](#) is vice president of information technology at Q2 Solutions, and is responsible for data to day operations, applications delivery and strategy for IT globally. He has over 25 years of IT management experience across several industries including 15 years in public health.

Previously, Mike was IT director for EA Genomics, and when it became an IQVIA company, he was IT senior director, with responsibilities for all production lab applications within the Central Lab, Genomics and BioAnalytical groups.

He has been with Q2 Solutions since 2011.

*Mike will co-present with Jian Wang.*

## Q<sup>2</sup> Solutions - data automation in the central lab

The scale and complexity of central lab operations have continued to grow which has led to a heightened demand for automation across data acquisition and processing workflows. Flow Cytometry has presented significant challenges based on the exponential increase in data volume. Anatomical Pathology in Central Lab requires flexibility to manage increased types of assays and study specific nuances.

Likewise, sample management and tracking present similar challenges in terms of volumes impacting handling and accuracy demands. These are some examples in central lab setting which are driving the need for data automation.

In this presentation we will discuss advancements Q<sup>2</sup> has made in these high value areas of operations by leveraging systems workflow and data handling for flow and AP as well as RFID pilot for sample tracking improvements.

# Claus Stie Kallesøe



[Claus Stie Kallesøe](#) is co-founder and CEO of grit42. Claus co-founded grit42 in 2014 after he headed Lundbecks Global Research Informatics group from 2000-2014. Claus currently sits on the board of directors of digital health/mental health company Monsenso and is a former board member of Pistoia Alliance.

Claus has a background in Medicinal Chemistry followed by a degree in software development and an E-MB Summary.

## Optimizing sponsor <> CRO laboratory data transfer

The big(ger) pharma companies have highly integrated internal systems and hence mostly have workflow support and data collection storage in place - although some areas like in vivo still seems to be underserved. However, the platforms are complicated and cannot easily be transferred to or shared with CROs for data input. The small(er) biotech companies very rarely have any internal systems in place that handles long term storage of the pre-clinical data in a FAIR manner. At the same time several of these biotech companies heavily rely on CROs for their data production Hence, these two - considerably - different customer groups have a data challenge in common: How to collect, align, aggregate, and store data from CROs in a FAIR manner, so they can:

1. Locate the datasets later
2. Analyze the data across different data producers
3. Import the data into their internal systems and analyze them alongside the internally produced data

At grit42 we have decided to focus on exactly that challenge. To deliver a platform that can easily be deployed in a secure manner, is simple to use and thus quick to get started with - also for the CRO data producers. At the same time, the grit42 platform is still advanced enough to be able to store data across the entire pre-clinical value chain, be it simple in vitro plate based assays or advanced in vivo studies with multiple dosing and animal level data.

The platform also supports several modalities and ability to configure the meta data on each modality type. Users can combine compounds with assay results in SAR table analysis, plot results to look for correlations, or export of the dataset for further analysis or AI projects. Examples GatesMRI/Foundation (antibodies, all CRO data); Contera Pharma (Oligos, CRO data + soon internal); IMI ERA4TB/COMBINE (small molecules; combinational therapy; 40 partners); IMI COMBINE (advanced in vivo studies incl. dosing and sampling activities).

## Alice Laures



[Alice Laures](#) is Director, product owner for GSK in the R&D Tech division with 19 years' experience in the pharmaceutical industry. Both a fully qualified pharmacist and chemical engineer, Alice spent 19 years in pharmaceutical R&D. She started her career supporting GSK anti-counterfeiting mission, worked with the Pharma supply chain to ensure security of supply, led analytical projects for drug substance development and spend 6 years in a leadership role in scientific and digital innovation before moving to Tech. In Tech, she supported the introduction of new capabilities to accelerate Biopharm discovery.

She is currently leading the creation and delivery of an agile strategy for Data Capture Automation to enable data analytics thereby providing R&D portfolio acceleration. She has a proven track record of strategy and flawless project delivery, extensive experience in project and people management (Agile & SAFe trained).

Most recently, she moved to a new role working on Chemistry Manufacturing & Controls (CMC) Grand Challenges. In addition to her day job, Alice is a member of the British Mass Spectrometry Society advisory board.

### Data capture automation: the 100 meters hurdles

Data Capture Automation is an enterprise solution developed to surface structured, standardized, quality instrument data in near real time. Combined with contextual data it enables operational efficiencies & deep learning in a robust, compliant & scalable manner. In this presentation, the author will describe the concept of the Research data fabric, present the vision, value proposition and the evolution of Instrument Data Capture Automation. Providing FAIR instrument data in near real time poses many challenges. The various successes, failures and learnings encountered along the journey will be shared.

## Xiangdong (Sean) Liu



[Sean Liu](#) is head of Scientific Assets & Decision Support within the Scientific Informatics department at Takeda.

Sean is a biologist by training and has worked in the bio/pharmaceutical industry for the past 20 years in the area of scientific informatics and data science. His team in Takeda is involved in unleashing the power of data by data integration, contextualization, visualization, exploratory analysis, and predictive modelling to support data driven decision making.

Sean will present the journey at Takeda to transform the bioassay management and analytics platform.

### The central role of scientific ontology in laboratory assay data harmonization

The key to the transformation is the development of a bioassay protocol management platform based upon the FAIR (Findable, Accessible, Interoperable, and Reproducible) data principles. This platform consists of an augmented Bioassay Ontology (BAO) with Takeda assay annotations, a Takeda minimum requirement for bioassay data annotation, a de facto industry standard of ontology management platform, and a newly developed assay protocol registration system.

This platform will harmonize Takeda's assay protocol registration and assay data management to significantly improve bioassay data's searchability and comparability. Moreover, the platform will increase data re-use and lay the foundation for various AI/ML predictive model development initiatives and empower data-driven decision-making.

## Christina Lu, MS



[Christina Lu](#) is Executive Director and Head of Data Management and Engineering, Development Science Informatics at Genetech.

## Shweta Maniar



[Shweta Maniar](#) is Director, Healthcare & Life Sciences Solutions, Google Cloud – BioPharma. Shweta is the strategic client lead responsible for Healthcare and Life Sciences. Shweta has quickly risen through the ranks as a well-known innovator, game-changer, and relationship ambassador.

With an 18+ year experience in clinical research, Healthcare and Bio Tech, she has proven time and time again how valuable relationships can be by enabling dozens of start-up firms with access to capital from Federal grants and VC firms alike. She brings an eye for detail, winning contract negotiations, and financial insight to support her commercial partnership strategy expertise. A position was created just for her, after excelling in a Commercial Partnering and Strategy role at Genetech.

She has been the recipient of multiple awards at Genentech, including two “Innovation Awards,” “MVP Award,” and more. Shweta brings an impressive network of established healthcare system relationships across Digital Health & Technology, Investor, Pharmaceutical, Medical Device, and Hospital Systems Industries.

She is passionate about keeping current with trends in medical devices, data, wearables, IoT, EHR, and machine learning. Since joining Google, Shweta develops and manages a variety of customer and partnership relationships while identifying new opportunities.

## Building labs of the future with the Cloud

Clinicaltrials.gov indicates that by 2025, there will be about 200K registered clinical trials. To power this number of trials, there would be at least 100 times (very conservatively) more leads that need to be identified and optimized.

Finding drug-like molecules that bind to a drug target is a critical step in the drug discovery process. Using target identification and lead optimizations scientists will be better able to design new and more potent drugs against diseases more efficiently and more cost-effectively than ever before. Computational approaches, like high-throughput virtual screenings, molecular dynamics simulations, and ML predictions are used to validate millions to even billions of drug-like molecules in silico before compounds are synthesized and tested in the laboratory, which can resolve current scalability reliability issues of running high performance and high throughput jobs and even identify de novo targets which otherwise could not be identified with current technology/methods. Technology is transforming drug discovery and how labs are leveraged throughout the process.

## Mike Montello, MBA



[Mike Montello](#) joined GSK in August 2018 as SVP, R&D Tech and is responsible for transforming the R&D Tech capability and platform. Mike partners with the R&D leadership team to focus technology resources to enable a step change in R&D science and performance, HCP and patient centric solutions, and simplification of processes and tools. He is accelerating the integration of the next wave of innovative technologies and agility while maintaining compliance and quality across R&D systems.

Previously, Mike was VP, Divisional CIO (Quintiles), and Global Head of R&D Information Technology for IQVIA, responsible for strategy and innovation initiatives that help R&D Solutions stakeholders accelerate clinical development, leverage evidence for protocol design and planning, improve operational execution, quality, patient safety, and investigator performance.

Prior to joining IQVIA in 2015, Mike led R&D Information Technology at Shire Pharmaceuticals, a global rare diseases biotech. As a member of Shire’s Information Technology leadership team, Mike led IT integration of multiple biotech acquisitions and led HCP and patient centric technology initiatives and strategic roadmap across R&D.

Prior to Shire, Mike worked at Accenture for 12 years as a management consultant and outsourcing leader in Health and Life Sciences practices. In addition to his industry role at IQVIA, he delivered innovative data and technology driven solutions for 6 of the top global Pharmaceutical and Healthcare companies including Pfizer, Merck, BMS, Biogen, Daiichi-Sankyo, and United Health Group. Mike holds a bachelor’s degree in Mechanical Engineering from the Pennsylvania State University and an Executive MBA from the London Business School.

## Leah O'Brien



[Leah O'Brien](#) is a wholehearted tech leader with passion, agility and a 20 year experience in the Pharma industry. She is a Senior Director in R&D Digital & Tech at GlaxoSmithKline.

As the Senior Product Director for Development Lab Systems, she has accountability for all GxP laboratory systems used across CMC development, as well as general lab instrument support across R&D. Leah leads a product-centric DevOps organisation, spanning development LIMS and ELN systems, CMC production data collection and analysis and Lab Engineering.

Leah has a BS in Computer Science from Carnegie Mellon University.

## Jay Rughani



[Jay Rughani](#) is an Investment Partner at Andreessen Horowitz ("a16z"), where he focuses on software-as-a-service, data, and marketplace companies across healthcare and life sciences.

Prior to a16z, Jay worked at Flatiron Health (acquired by Roche). There, he helped to build some of the company's first data & analytics software products used by biopharmaceutical companies to study real-world cancer care. He went on to develop numerous commercial partnerships with large biopharma companies, smaller biotechs, and other research organizations. Previously, Jay advised large healthcare and technology organizations on corporate growth initiatives at Deloitte and supported various go-to-market, product, and fundraising efforts at DealerMatch (acquired by Cox Enterprises).

Jay received a BA in Mathematics & Economics at Emory University and grew up in Clearwater, FL, and London, UK.

## David Sedlock, PhD



[David Sedlock](#) retired in 2019 as the Global Head of Research IT at Takeda Pharmaceuticals Ltd. where he was responsible for the planning, development and management of software application platforms supporting the company's drug discovery and early clinical programs. This included application development, design, deployment, integration, and support for the various systems and services used by the Research and Early Development scientific staff including bioinformatics, cheminformatics, LIMS, and GLP systems.

David is currently engaged in various consulting activities including a commitment to the PRISME Forum organization managing various project work to further the mission of the Forum.



# Etzard Stolte, PhD



[Etzard Stolte](#) is leads the global Information/Knowledge Management effort in Pharma Technical Development for F. Hoffmann-La Roche in Basel, with a focus on processes and tools for effective knowledge utilization.

Etzard has worked at the interface of the life- and computer-sciences for more than 20 years, in technical, managerial as well as strategic roles. Before joining Roche, Etzard worked as CIO for the Jackson Lab (a US-based genomics research institutes with 1800 employees) and was CTO for Life Sciences at Hewlett Packard.

Etzard has earned academic degrees in both Biology, Bioinformatics and Informatics, with a PhD in Computer Science from ETH Zurich on "A Scalable Architecture for Scientific Databases".

# Lee Tessler, PhD



[Lee Tessler](#) is an AWS Principal Tech Strategist for the Life Sciences industry. His focus is on novel cloud architectures to address some of the hardest problems across the Life Sciences, including modern R&D data strategy, computer-aided drug design, decentralized clinical trials, and modernized manufacturing. Lee is a scientist by training and has spent most of his career in product management for the life sciences. Prior to joining AWS, he designed, built and launched software products for bioinformatics, drug discovery, clinical diagnostics, smart instruments and pharma manufacturing. Lee holds a Ph.D. in computational biology from Washington University in St. Louis and Sc.B. from Brown University.

## AWS - creating digital connected labs that scale

Sciences customers see computational methods as a way to increase the performance, throughput, and effectiveness of their lab operations. This presents opportunities around long-standing challenges with experiment reproducibility and the ability to address lab workflow inefficiencies via automation and predictive analytics. The need to securely share information beyond corporate walls is urgent; collaboration continues to be a key approach to drug development. As precision medicine evolves, the need to evaluate large, complex datasets, such as genomic data or medical imaging, requires the use of artificial intelligence or machine learning technologies to derive insights from large quantities of data.

The AWS Cloud is moving quickly in this area and has purpose-built services, partner solutions, and accelerators to digitalize labs operations in the cloud. AWS provides a unified vision around data capture, ingestion, storage, analytics, and AI/ML capabilities to empower the modernized biopharma lab. In this session, you will learn about the overall capabilities and direction of the AWS data strategy which is the foundation for building and operating digital labs of the future. We will share best practices for how Life Sciences companies are benefitting from the virtually unlimited scale and agility when it comes to operating their digital labs in AWS cloud.

## Jian Wang, PhD



[Jian Wang](#) is Vice President and Head of Innovation, where he develops, directs and implements the Q<sup>2</sup> Solutions' innovation. Previously, he was the CEO of BioFortis, the Q2 Solutions precision medicine and technology solutions company.

For more than 20 years, Dr. Wang developed several software products with pharmaceutical customers, government agencies, and academia. He has deep knowledge in the rapidly evolving field of precision medicine and its associated biomarker-driven clinical trials, and strives to bring precision medicine technology solutions to researchers to help solve real-world health problems.

Dr. Wang has a PhD in bioengineering from the University of Washington.

*Jian will co-present with Mike Hamill on Q<sup>2</sup> Solutions - Data automation in the central lab.*

## Sajith Wickramasekara



[Sajith Wickramasekara](#) is Founder & CEO at Benchling. Established in 2012, Benchling was designed to be a digital version of a scientist's lab notebook. A year later, when Sajith appeared on the Forbes Under 30 list, the biotech R&D software startup had raised \$6 million at a valuation of \$17.5 million.

Today Benchling has more than 600 customers, including Regeneron, Sanofi and Syngenta. It is worth \$6.1 billion following a recent financing round led by Franklin Templeton and Altimeter.

Sajith attended MIT where he earned a Bachelor's degree in Electrical Engineering and Computer Science.

## John Wise, MA



[John CM Wise](#) is the Program Coordinator for the PRISME Forum and is also a consultant at the Pistoia Alliance with responsibilities that include business development and member relations. He specializes in the coordination of pre-competitive collaborations in life science R&D IT and has had a long-time commitment to encouraging pharma to use expert, third-party, cost-effective, regulatory-compliant, secure, hosted information services.

Previously, John has held Informatics leadership roles in a variety of organizations including the University of London, Sandoz, the Imperial Cancer Research Fund (now CRUK), Roche, Ipsen and Daiichi Sankyo. He has also worked in the technology supply side of the industry. In these roles, he has gained direct hands-on experience writing analytical software, teaching computation, delivering IT services, and providing computer-based services to the discovery, non-clinical development, clinical development, and regulatory affairs domains of the life-science industry.