

PRISME Forum

Pharmaceutical R & D Information Systems Management Executives

PRISME Forum

BUSINESS AND TECHNICAL MEETINGS

Japan Group

PRISME Forum Chair:

Dan Chapman

Head, IT Early Solutions Information Management, UCB

November 16-19, 2020

Online

PRISME Forum Business Meeting Board of Directors

Dan Chapman

Chair, *PRISME Forum*; Head, IT Early Solutions Information Management, *UCB*



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

After completing a PhD in Chemistry at Warwick University, Dan transitioned to informatics during post-doctoral research at Cambridge University as part of the CLIC consortium.

Dan joined AstraZeneca in 1997 and worked on a variety of global projects before joining UCB in his present role in 2005. Since then, Dan has driven several projects to revolutionize the informatics platform within UCB and is currently actively involved in promoting Data Science across UCB.

Christian Baber

Head, Scientific Informatics, *Takeda*



Christian Baber, PhD, 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 as a computational chemist and cheminformatician.

Christian has a wide breadth of experience across companies ranging from startups to Pfizer and diverse therapeutic areas with a focus on early stage lead identification and screening. Christian has been with Shire between 2015 and 2019 and is currently the Head of Scientific Informatics at Takeda.

Prior to Shire, Christian was the Head of Cheminformatics and Compound Management and Data Steward at Cubist Pharmaceuticals where, amongst other things, his team was responsible for automation, high-throughput screening, scientific programming and the corporate scientific database.

Alastair Binnie

Vice President, R&D IT, *Bristol-Myers Squibb*



Alastair Binnie is Head of Information Technology for Research & Development at Bristol-Myers Squibb. In this role he is accountable for planning and delivering all aspects of IT's value proposition to BMS R&D, which includes digital platforms supporting discovery, preclinical, translational medicine, clinical development, regulatory sciences, pharmacovigilance, and medical affairs. His mission is 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, assuming his current role in 2015. 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 represents 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.

Martin Erkens

Head, pRED Informatics, *F. Hoffmann-La Roche*



Martin Erkens, PhD, leads the Pharma Research and Early Development Informatics organization (pREDi) of Roche. Data science supporting drug projects as well as Research and Early Development workflow solutions are among the key contributions of his organization.

He was responsible for supporting multiple mergers and acquisitions, implementing a wide range of diverse solution including a digital media environment for early development, a research imaging data warehouse, an efficient data review tool for early clinical studies and a LIMS for the omics labs.

Prior to becoming head of pREDi, Martin ran various IT teams in the clinical space and was responsible to implement global systems for drug project and portfolio planning, global sales reporting, electronic data capture of clinical trials (the first

large cloud system at Roche), clinical imaging and a system environment for the internal clinical Phase I unit.

During this time he also led a program establishing a complete new blue print of the system landscape supporting clinical development resulting in an investment program over 5 years and 100+ mUSD investment.

Martin received his PhD in Mathematics (stability theory) from the Albert Ludwigs University in Freiburg. He also holds two degrees in Mathematics and Physics ("Diplom" and "Staatsexamen") from the same university.

Andreas Friese

Head, R&D-IT Early Development,
Pharma-Research, *Bayer*



Andreas Friese, MS, started his professional career as a software developer in 1987 at Schering AG, Berlin, Germany. From the beginning, he focused on IT solutions that addressed specific needs of the Research organization. Over the years, he held various positions as system analyst and project manager – all with focus on

Research specific systems or projects.

In 1999, Mr. Friese moved to Richmond, CA, USA as an IT Business Partner for the Medicinal Chemistry department of Berlex Biosciences. During the merger of Schering AG with Bayer AG, he returned to Germany. Based in Wuppertal, he is Director of Research-IT Early Development for Bayer.

Lars Greiffenberg

Director R&D Information Research, Library
Sciences & Academic Partnerships, *AbbVie*



Lars Greiffenberg, PhD, MS, holds a MS in Biology and a PhD in Microbiology and has more than 15 years of experience in the field of integrated R&D IT solutions and translational informatics. He held different R&D IT management positions at Aventis Pharma and Sanofi-Aventis in Frankfurt before relocating to the Sanofi

site in Toulouse, France where he was Global Head of Solution Center Translational Medicine with responsibility to manage and lead a global program to enable translational science at Sanofi. In 2014 he joined AbbVie in Ludwigshafen (Germany) as director of R&D IT and Translational Informatics. In this role he is heading business IT support covering data and solutions from early discovery up to Medical Affairs. In 2017 he extended his responsibilities including now global Library Sciences at AbbVie.

He is driven by the ambition to transform the way we access, consume and leverage literature in the future. He recently established a team at AbbVie, dedicated to use

modern methods and algorithms to extract and visualize mechanistic disease information from literature content. In 2018 he further enlarged his area of responsibility to incorporate the Academic Partnerships Organization which is leveraging an AbbVie-Campus at the University of Illinois Urbana-Champaign.

Lars is active in several pre-competitive organizations including IMI, PRISME Forum, Pistoia Alliance and EIT-health.

Tomoyuki Matsunaga

Head, Research Management Systems, Research IT,
Takeda



Tomoyuki Matsunaga is Head of Research Management Systems in Global Information Technology at Takeda Pharmaceutical Company. His role is to lead any strategic IT operations for common management processes and workflows of research activities in conjunction with other functional research IT groups, such as

Discovery, Preclinical and Translational Sciences. He is also the site IT manager at Shonan Research Center in Japan.

Tomo started his career in Central Research of Pfizer Japan in 1991 as a research scientist. After 5 years in Natural Product Screening department, he moved to Research IT group in the company and worked on various projects of global discovery research information systems. He joined Takeda in 2008 as an Associate Director in Research IT and took the current position in 2014.

He obtained his MBA from Kenichi Ohmae Graduate School of Business and MSc, Medical Sciences from University of Tsukuba.

Mike Montello

SVP R&D IT, *GlaxoSmithKline*



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.

Scott Oloff

Executive Director, IT R&D and Medicine Enablement, *Boehringer-Ingelheim*



Scott Oloff, PhD, started his career as a Computational Chemist in Research where he worked for both Biogen and Boehringer Ingelheim.

His primary expertise was building and using machine learning algorithms for potency/ADMET predictions, docking, and research project support. In 2008 he took a position in Research IT within Boehringer Ingelheim overseeing data analytics and mining technologies.

Over time he has expanded into a number of IT R&D roles where he now oversees all technologies that are shared across the Research, Development, and Medicine business areas (Analytics, Chemistry tools, ELN's, Lab technologies, LIMS, Document Management tools, etc.).

Scott holds a bachelor's degree in Chemical Engineering from Clemson University and a PhD in Pharmacology from the University of North Carolina.

Errol Sandler

VP, Board Secretary/Treasurer, *PRISME Forum*



Errol Sandler, PhD, worked in the information technology industry for 30 years.

His career focused on R&D computing problems in the life sciences as well as leadership and technical expertise for R&D computing in the pharmaceutical industry.

He led teams to provide information technology support at several Pfizer Global research and development sites in the United States and the United Kingdom.

Dr. Sandler received his PhD in Physics and Astronomy from the University of Missouri-Columbia.

Susie Stephens

Senior Director, Analytics & Master Data Architecture, *Pfizer*



Susie Stephens, PhD, is a strategic leader in the pharmaceutical industry with over two decades of experience in informatics, science and technology. She is currently Senior Director, Analytics and Master Data Architecture at Pfizer.

Prior to that she was Head of In Silico Immunology at Johnson & Johnson for the Immunology Therapeutic Area.

She has also worked at Oracle and Sun Microsystems where she had roles spanning pre-sales, product management and business development.

Susie has a PhD in Physiology; post-doctoral experience in Molecular Biology; and is an alumnus of Harvard Business School. She has over 20 peer reviewed papers and has presented at many industry conferences on data, advance analytics, precision medicine, and innovation. Susie is the founding Chair of the PRISME Forum.

John CM Wise

Program Coordinator, *PRISME Forum*



John Wise, MA, 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, Mr. Wise 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.

PRISME Forum Statement of Compliance

“All meetings, working groups and communications will be open to all Members and any records thereof will be non-confidential and available for inspection by any Member. The Members acknowledge that discussing any commercially sensitive topics, including costs, volumes, inventories, sales level methods, channels of distribution, access to future products, markets, current or future prices, profitability, **contract pricing or trading terms** is prohibited. The Members of PRISME will strictly comply with all laws relevant to their activities, including US state and federal anti-trust laws and European competition laws.”

Company Updates

CONTENT

One of the key activities of the PRISME Forum meetings is the “Company Updates.” These updates allow members to identify common key themes from across our companies such as:

- industry trends
- common business drivers
- challenges
- IT initiatives
- areas of investment, and
- opportunities for pre-competitive collaboration.

Members often include in their company updates the following kinds of information:

1. High-level company overview with emphasis on R&D priorities and key business drivers of R&D IT strategy, practice and emerging trends
2. R&D IT/Informatics organization overview with emphasis on key IT/informatics areas of focus for strategy, implementation and process improvement
3. Any useful benchmarking data (e.g. R&D IT/Informatics expenditure as a percentage of the R&D budget, R&D IT skills portfolio/skills gaps)
4. And most IMPORTANTLY - anything else a member would like to share or get advice about

It is important to note that the spirit of company updates is pre-competitive, collaborative and is informal. As such, no formal minutes for these discussions are produced or published. The PRISME Forum is very aware of its responsibilities to avoid any perception of anti-competitive practices. As such the PRISME Forum conducts all of its activities in conformance with all international, U.S. federal and state antitrust laws.

STRUCTURE

For the company updates, the PRISME Forum members will be divided into several subgroups. Each subgroup will have a group captain to host and facilitate the discussion. PRISME Forum members will provide their company updates within the subgroups. (90 minutes)

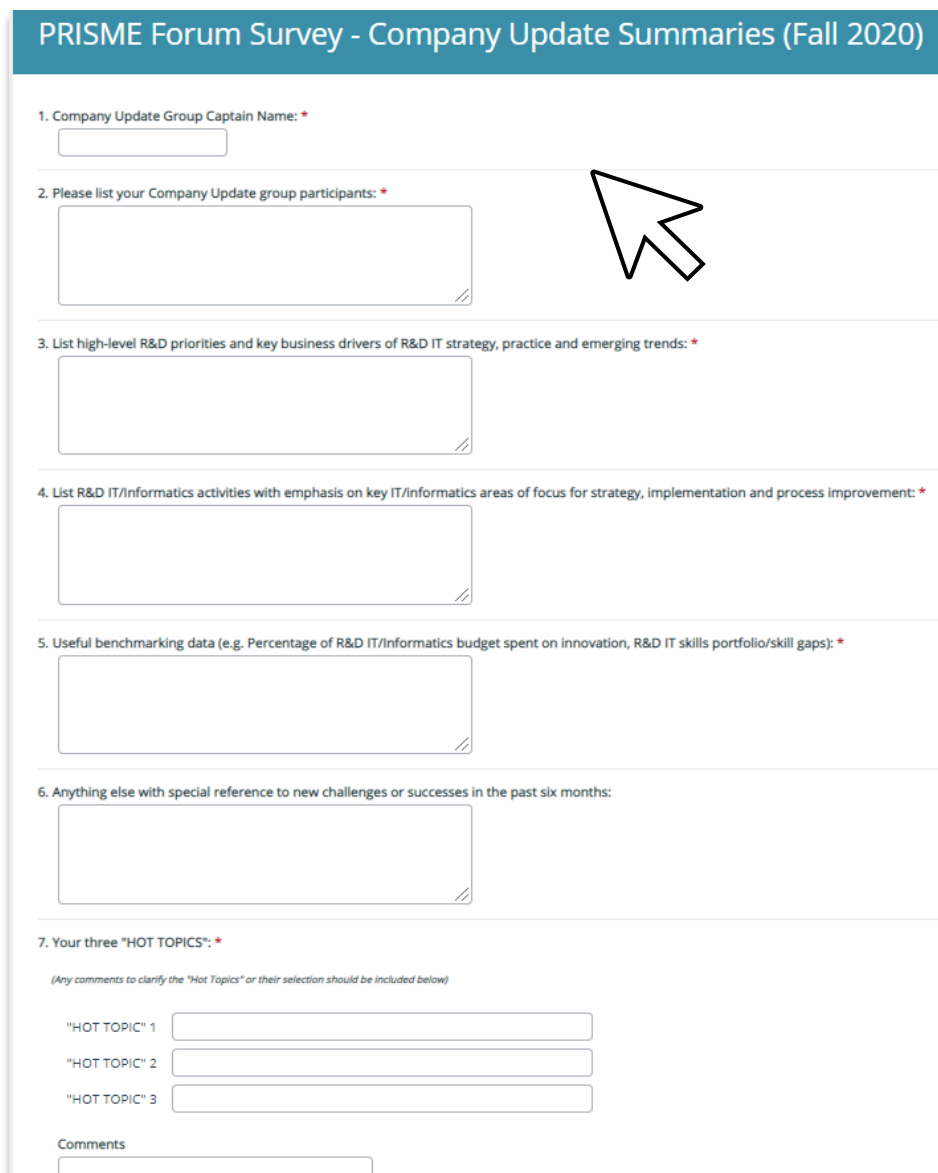
PRISME Forum members will summarize the key points. (30 minutes)

Group captains will use the survey at

<https://survey.alchemer.com/s3/5990423/PRISME-Forum-Survey-Company-Update-Summaries-Fall-2020>

to submit the key points for a plenary presentation and discussion.

The plenary session of Wednesday will allow group captains to present their group's key points and up to three (3) "hot topics" proposed for the Spring 2021 Technical Meeting. (75 minutes)



The image shows a screenshot of a survey form titled "PRISME Forum Survey - Company Update Summaries (Fall 2020)". The form is divided into seven numbered sections, each with a text input field. A mouse cursor is pointing at the second section. The sections are:

1. Company Update Group Captain Name: *
2. Please list your Company Update group participants: *
3. List high-level R&D priorities and key business drivers of R&D IT strategy, practice and emerging trends: *
4. List R&D IT/Informatics activities with emphasis on key IT/Informatics areas of focus for strategy, implementation and process improvement: *
5. Useful benchmarking data (e.g. Percentage of R&D IT/Informatics budget spent on innovation, R&D IT skills portfolio/skill gaps): *
6. Anything else with special reference to new challenges or successes in the past six months:
7. Your three "HOT TOPICS": *
(Any comments to clarify the "Hot Topics" or their selection should be included below)
"HOT TOPIC" 1
"HOT TOPIC" 2
"HOT TOPIC" 3
Comments

@Group Captains: Please click above image or link to access the survey

Program – Japan Time

BUSINESS MEETING

reserved exclusively for PRISME Forum members and their delegates

MONDAY, November 16, 2020

10:00 COMPANY UPDATES

11:30 Break

11:45 GROUP SUMMARY

12:15 End of day for the Japan group

12:15 Japan Group Captain uses template to prepare key points

13:00 Japan Group Captain submits survey on key points for PRISME Forum Chair's review

17:00 Japan Group Captain conference call with PRISME Forum Chair

17:30 End of day for Japan Group Captain

BUSINESS MEETING

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WEDNESDAY, November 18, 2020

21:00 GROUP CAPTAINS' UPDATES

10 groups with 3 minutes per group presentation; topics presented will be the ones reported to the PRISME Forum Chair in prior days.

21:30 COMPANY UPDATE REVIEW, SUMMARY AND SELECTION OF "HOT TOPICS"

Dan Chapman, Chair, PRISME Forum; Head, IT Early Solutions Information Management, UCB

BUSINESS MEETING ACTIVITIES

22:30 PRISME Forum Roadmap
PRISME Forum Brief Financial Report
PRISME Forum Leadership Election
Software Survey
For discussion/possible SIG - the NBE (Novel Biological Entity) Data Sharing and Mining

Dan Chapman, Chair, PRISME Forum; Head, IT Early Solutions Information Management, UCB
Errol Sandler, Treasurer/Board Secretary, PRISME Forum
David Sedlock, Project Coordinator, PRISME Forum
John Wise, Program Coordinator, PRISME Forum

23:30 GSK Presentation (with Q&A)

Kim Branson, SVP Global Head of Artificial Intelligence and Machine Learning, GSK

00:15 End of Business Meeting

TECHNICAL MEETING

reserved exclusively for PRISME Forum members, their delegates, and invited speakers

THURSDAY, November 19, 2020 (Note: Sessions will be recorded)

Digital-enabled change in R&D & Healthcare as triggered by COVID-19

The biopharmaceutical industry, similar to many other industry sectors, has been severely impacted by the demands of the COVID-19 pandemic. This crisis has forced biopharmaceutical companies and their business partners to re-think their approaches to pharmaceutical R&D. Senior management in the biopharmaceutical industry has come to see the IT infrastructure as the technology for keeping the business running; what used to be widely perceived as a cost is now viewed as an opportunity!

Rapidly improving teleconferencing technologies are providing the medium for meetings and also cutting down on the costs and time of travel. The nascent trend away from the “physical” world towards the “virtual” world, that had been slowly evolving, has now experienced a leap forward and is likely to become a feature of the “new normal”.

Clinical trials can be reimagined focusing on optimizing the patient journey while enhancing the investigator experience. Some clinical trials that used to require patients to visit the clinical trial center can be re-engineered as decentralized, virtual clinical trials exploiting the wealth of smart technologies such as phones, wearables and home tests. Indeed, the practices of obtaining informed consent could become home-based using telecommunications, videos, electronic signatures all perhaps founded on blockchain technology. Real World Data (RWD), coupled with state-of-the-art, AI/ML-powered analytics tools, could allow for virtual control arms in clinical trials thereby encouraging patient participation while increasing speed and decreasing cost. RWD could enhance the identification of the right patients, in the right places, with the right inclusion / exclusion criteria, known to the right investigators and better address the urgent need for appropriate diversity within the cohorts of clinical trial subjects.

Pharmaceutical discovery laboratories may also be re-imagined. Shift working can be introduced to enable social distancing, while maintaining productivity. “Cloud-based” laboratories can be utilized too, thereby shifting some of the burden of COVID-19 requirements to these specialist centers. This Fall 2020 PRISME Forum Technical Meeting will explore these changes that have been incorporated into pharmaceutical R&D processes and will seek to identify some emerging opportunities including products and services that will accelerate the efficiency and effectiveness of R&D in these constrained times and going forward into the “new normal”.

01:00	<i>Technical Meeting Introduction</i>	Dan Chapman , Chair, PRISME Forum; Head, IT Early Solutions Information Management, <i>UCB</i> Alastair Binnie , Chair, PRISME Forum Technical Meeting; Vice President, R&D IT, <i>BMS</i>
01:05	KEYNOTE PRESENTATION: Why There's Never Been a Better Time to Impact your Business as an R&D Technology Leader	Diana McKenzie , Technology Executive, Board Member, and Former CIO
01:45	Healthcare Is Bringing Hospital to Home--Is Pharma's R&D Ready? Jaydev Thakkar , Chief Operating Officer, <i>Biofourmis</i> For many years, healthcare ecosystem has been brewing the changes - Can we move from episodic care to continuous care? Can we move from break fix to predict and prevent? Can we move to value-based contracts instead of fee for service models? Can we make healthcare personalized? Can we shift more of the care to patient's home? Combination of medical grade (and patient friendly!) wearable sensors and AI/ML predictive tools have made this a real opportunity for transformation, and Covid-19 has provided the final push! Hospital at home is here! From acute care management to post-acute transitive care and chronic condition management! So, how does it matter to Pharma's R&D? R&D timelines can be shortened by a few years or will get stretched. What new capabilities are needed to capitalize on these trends and do you need to buy or build? <ul style="list-style-type: none">• New care pathways and patient journey -> new patient recruitment challenges and strategies for clinical trials• Continuous monitoring -> novel biomarkers and endpoints, new protocol designs• Predictive AI/ML tools -> redefined disease diagnosis, personalized new triggers for intervention and dose titration	

	<p>strategies</p> <ul style="list-style-type: none"> • New tools for efficacy, QoL and safety measurements -> from "nice to have" to "must have"! • Digital therapeutics -> combo therapies and companion therapeutics
02:25	<p>PANEL DISCUSSION</p> <p>Hall Gregg, PRISME Forum (Panel facilitator)</p> <ul style="list-style-type: none"> • Amrik Mahal, Global IT Head for Research, AstraZeneca • David Neilson, Senior Director, R&D Information Technology, <i>Gilead</i> • Mark Buswell, VP Technology Vaccines, GSK • Matteo di Tommaso, VP Medical and R&D ITS, Sanofi
03:15	<p><i>End of Technical Meeting Day 1</i></p> <p>Alastair Binnie, Chair, PRISME Forum Technical Meeting; Vice President, R&D IT, <i>BMS</i></p>

TECHNICAL MEETING

reserved exclusively for PRISME Forum members, their delegates, and invited speakers
THURSDAY, November 19, 2020 (Note: Sessions will be recorded)

21:00	<p><i>Day 2 Opening Remarks</i></p> <p>Alastair Binnie, Chair, PRISME Forum Technical Meeting; Vice President, R&D IT, <i>BMS</i></p>
21:05	<p>KEYNOTE PRESENTATION</p> <p>Dónal Landers, Director, Digital Experimental Cancer Medicine Team (digitalECMT), <i>Cancer Research UK Manchester Institute/The Christie NHS Foundation Trust</i></p>
21:45	<p>PRESENTATION – Microsoft</p> <p>Geralyn Miller, Director, Health Strategy, <i>Microsoft AI for Good Research Lab</i></p> <ul style="list-style-type: none"> • Learning from the White House Covid19 HPC Consortium: cross-sector collaboration • When days matter: massive compute at your fingertips • Data Sharing: the good, the bad and the ugly • Digital Research Environments: coming of age in the Covid19 era
22:25	<p>LIGHTNING TALKS</p> <p>Alastair Binnie, Chair, PRISME Forum Technical Meeting; Vice President, R&D IT, <i>BMS</i></p>
22:25	<p>Frontiers: From Genomic England's New Federated Research Environment to Top Pharma's Novel Disease Surveillance System</p> <p>Maria Chatzou Dunford, PhD, CEO/Co-founder, <i>Lifebit.AI</i></p> <p>COVID has completely changed the way we are doing things. When it comes to developing drugs and therapies, COVID has put an absolute spotlight on population health, emphasizing the critical need for rapid access and effective utilization of population-level clinico-genomics data. This, combined with the ability to predict and anticipate disease outbreaks, have emerged as critical in winning fights against infectious diseases, like COVID. Lifebit has been a pioneer in helping governmental organizations, like the UK Government and Genomics England, and top 10 pharma companies to successfully access and utilize population-level clinico-genomics data and predict future disease outbreaks.</p>
22:35	<p>Changing Clinical Trial Participation – Patient Engagement and Trial Design</p> <p>Ronnie Du, SVP of Analytics, Clinical Trial Solutions at Hū</p> <p>At Hū our mission is to unlock human behaviors as an accelerator to clinical trial innovation. Despite slight improvements to cycle time over the last 5 years, clinical development remains the primary bottleneck in advancing new medicines to market.</p> <p>Now, almost a year into it, we've seen COVID-19 implications play out in clinical research and a dichotomy emerge. COVID-19 vaccine and treatment trials have been planned and conducted at unprecedented speed while non-COVID trials slowed to a halt and are still struggling to recruit and retain patients. Ultimately, it comes down to a deeply personal and multi-factorial decision as to whether to participate in a clinical trial.</p> <p>This presentation will convey the power of a personalized human approach aimed at understanding the patient and their level of activation, driving literacy and education, and ultimately raising health citizenship overall and engagement, equity and participation in clinical trials specifically.</p>

	<p>In the presentation we will cover:</p> <ul style="list-style-type: none"> • Problem statement and challenges above (with statistics) • Behavioral Economics: The human behavioral factors that are critical to understand for decision-making and removal of barriers • Hū Biomarker: Assessment of medical and behavioral characteristics to inform activation and patient engagement • The impact of meeting people where they are and engaging them before and after they become potential patients, some examples • What Hū is focused on now: Our patient engagement platform that includes protocol design crowd-sourcing, ICF A/B testing, and broader mechanism for patient input
22:45	<p>4G Clinical</p> <p>Ed Tourtellotte, Clinical CTO, <i>4G Clinical</i></p> <p>Modern Technology Enables Speed & Agility in Midst of Pandemic</p> <ul style="list-style-type: none"> • Speed – How Natural Language Processing (NLP) enables fast-moving COVID trials & massive FDA amendments • COVID Response – Use of mini languages and highly configurable system elements to facilitate Direct-to-Patient (DtP) • Patient Privacy – Protecting blinded and highly confidential information when shipping to patient’s homes
22:55	<p>Enabling the Future—How Decentralized Clinical Trials are Advancing Research During COVID-19 and Beyond</p> <p>Chris Ceppi, Chief Product Officer, <i>Science 37</i> Marina Perrin, Senior Director, Business Development, <i>Science 37</i></p> <p>With COVID-19, the adoption of decentralized clinical research is accelerating as sponsors explore ways to leverage technology and maintain continuity while looking toward the future for more effective and productive research. Regulators agree, saying some of the changes will represent an acceleration of where we were headed before, including support for decentralized clinical trials.</p> <p>During this 10-minute presentation, we’ll describe the benefits of technology in decentralized clinical trials to accelerate drug development and expand patients’ access to clinical studies. We’ll also highlight the patient journey for a decentralized clinical trial—sharing how the use of an orchestrated DCT model and best-in-class technology is broadening treatment for this patient population.</p>
23:05	<p>ePRO</p> <p>Ashley George, PhD, Professor, <i>UCL</i></p> <p>Creative Digital Engineers puts citizens first. After all, a patient can be considered a citizen who is having a bad day! Access to healthcare and specifically to health information, irrespective of geolocation, healthcare system, literacy, socio-economic status, etc. should be considered a human right. [United Nations, Sustainable Development Goals, UN SDG #3, WHO - Health is a fundamental human right].</p> <p>Within this ethos [UN SDG #3, #4 & #10] Creative Digital Engineers and its global, citizen-first approach, has “accidentally” created an instantly-available, zero-download, minimalist infrastructure that is already in use and familiar to ~3.9Bn citizens. There is an opportunity, with PRISME Forum’s assistance, to realise and sustain a global ePRO with direct citizen engagement to capture Real World Data – and its derivative Real World Evidence - that is NOT yet another app! This approach benefits both patients and the biopharmaceutical industry. From the patients’ perspective, much of the complexity and diversity that patients find when they engage with the highly-fragmented biopharmaceutical industry is minimised. From the biopharma perspective, much of the technology diversity and complexity of engaging with global citizens is minimised – thereby allowing resources to be focused on trial design, setup and data analysis rather than launching yet another piece of bespoke technology for data collection.</p>
23:15	<p>Panel Discussion with Poster Presenters</p> <p>Alastair Binnie, Chair, PRISME Forum Technical Meeting; Vice President, R&D IT, <i>BMS</i></p>
23:35	<p>Closing Remarks</p> <p>Alastair Binnie, Chair, PRISME Forum Technical Meeting; Vice President, R&D IT, <i>BMS</i></p>
23:40	<p>Closing Notes</p> <p>Dan Chapman, Chair, <i>PRISME Forum</i>; Head, IT Early Solutions Information Management, <i>UCB</i></p>
23:45	<p><i>End of Technical Meeting</i></p>

SHORT BIOGRAPHIES

Alastair Binnie, MSc



Alastair Binnie is Head of Information Technology for Research & Development at Bristol-Myers Squibb. In this role he is accountable for planning and delivering all aspects of IT's value proposition to BMS R&D, which includes digital platforms supporting discovery, preclinical, translational medicine, clinical development, regulatory sciences, pharmacovigilance, and medical affairs. His mission is to enable R&D by providing the right tools and the right data, to the right scientists, at the right time. He is currently kept quite busy with the challenge of leading one of the industry's largest integration of digital capabilities for R&D.

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, assuming his current role in 2015. 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 represents BMS on the New Jersey Technology Council. Alastair 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.

Kim Branson, PhD



Dr. Kim Branson joined GSK April 2019 as Senior VP and Global Head of AI/ML. Kim Branson has been involved in large scale machine learning and medical informatics initiatives for over 16 years, over a range of ventures from computational drug design to disease risk prediction.

Prior to joining GSK, Kim was Head of Artificial Intelligence for the Informatics department of Early Clinical Development at Genentech. He also served as Founding Chief Data Scientist at Lumiata, a predictive health analytics company.

Kim received degrees from the University of Adelaide, and a PhD from the University of Melbourne. He was a Peter Doherty fellow and received postdoctoral training at Stanford University. He held leadership and consulting roles in the pharmaceutical and medical informatics industry, notably at Vertex Pharmaceuticals. Following this, Kim worked extensively in online search as a founding member of Discovery Engine (acquired by Twitter in 2009) and in Health Informatics as the Founding Chief Scientist of Glimpse (acquired by Apple in 2017).

Mark Buswell, PhD, MBA



Mark Buswell is the Head of Vaccines Tech at GSK, recently transitioned from VP of Research Solutions in R&D Tech, GSK. In his latter role, he had the accountability for all pre-clinical Tech solutions supporting R&D from target sciences, through discovery and development, and finally to clinical trial supply.

He joined GSK in 2002 and has held roles in R&D and manufacturing in process development and engineering, innovation and sustainability, and more recently moved into the R&D Tech function.

He has a PhD in Chemical Engineering from University of Cambridge and an MBA from Cranfield University. His interests include pharma R&D information technologies, synthesis of APIs using novel methods, novel formulation technologies, fermentation technologies, advanced analytical technologies and automation.

Mark is a chartered Chemical Engineer, a Fellow of the Institute of Chemical Engineering, a Fellow of the Royal Academy of Engineering and a Board Director of the Pistoia Alliance.

Chris Ceppi



Christopher Ceppi is Chief Product Officer of Science 37. He is an executive and technologist with more than 20 years of experience building and leading teams dedicated to innovation. He is a recognized thought leader in how best to apply technology to advance the conduct of clinical research in ways that benefit both patients and scientists.

As chief product officer at Science 37, Christopher leads the technology organization at Science 37 and drives the design and development of the groundbreaking Science 37 platform. He oversees the teams responsible for software engineering, product management, and data science.

Maria Chatzou Dunford, PhD



Dr. Maria Chatzou Dunford is the CEO and co-founder of Lifebit.AI. Maria is a thought-leader and biotech innovator, expert in AI-driven drug discovery, biomedical informatics and federated computing. She is also a passionate entrepreneur and has founded two companies, Innovation Forum Barcelona and Techstars-backed Lifebit.

Prior to Lifebit, she was a biomedical researcher, working on developing tools and methods that facilitate the analysis of Big Biomedical Data and promote personalized medicine discoveries. This includes the industry's standard programming framework, Nextflow, that has revolutionized the computational analysis of genomic data.

Maria is also a frequent industry speaker and has spoken in many international conferences on the subjects of genomics workflows, the computational challenges of personalized medicine, AI, Cloud and HPC in genomics and drug discovery, women in leadership, entrepreneurship, science ventures, among many other topics.

Matteo di Tommaso



Matteo di Tommaso is the Head of R&D and Medical Digital at Sanofi. He and his team use data, information and technology to have positive impact on the discovery and development of new medicines and bringing those medicines and effectively to patients and healthcare providers.

Matteo has diverse experiences leading technology teams in pharma & building products and services that benefit the pharmaceutical industry at Biogen, Pfizer, Celera Genomics, Genetics Computer group, the European Bioinformatics Institute. Matteo and the teams that he has led have also contributed to multiple cross-industry initiatives and created source products.

Matteo began his career at Warner-Lambert working on automation and pre-clinical information systems with a degree in Chemistry from Indiana University.

Ronnie Du, MBA



Ronnie Du specializes in biopharmaceutical R&D data strategy and data-driven clinical program design and planning where he has helped clients maximize the value of their internal and external data assets to drive meaningful business outcomes. He has led several large-scale business transformation initiatives that enabled data-driven R&D business processes from clinical evidence planning through lifecycle management.

Ronnie has in-depth knowledge of clinical, real world, and social data, and the techniques and opportunities for bringing them together for generating new scientific and business hypotheses, reinforcing claims, and driving productivity.

Ronnie has over 15 years of biopharmaceutical industry experience at the intersection of clinical development, technology, and analytics. Most recently Ronnie helped to build the R&D Clinical practice area at ZS Associates including leading several life science R&D strategy and advanced analytics programs. Prior to ZS Associates Ronnie held positions in clinical development, information technology, and data sciences at Amgen.

Ronnie has a Bachelor's degree in electrical engineering and computer science and a Masters in Business Administration, both from the University of California Los Angeles.

Ashley George, PhD, FRSC



Prof Ashley George is an old and cynical chemist who has spent much of his career in the global biopharmaceutical industry. His last engagement with the PRISME Forum was back in the days of PRISM – before it merged with PRIME - at its meeting held at Biovitrum in Stockholm in 2010.

Ashley is also a co-founder and the Treasurer of the Pistoia Alliance. In 2018, Ashley was lucky enough to be placed on “gardening leave”. As such, he had the opportunity to reflect on 23 years or so of Pharma & Lifesciences global “transformation” and take a long, harsh, stark, cynical- chemist’s retrospective, of all those career trials and tribulations!

Ashley now has developed a global portfolio career, including being President of TechForGood.org, a Visiting Chemistry Professor at University College London, and CEO of Creative Digital Engineers, a company that is staffed by battle-hardened, pragmatic technologists who are not looking to “build a unicorn” but rather to “leave a legacy”. After all, why should millennials have all the fun!

Hall Gregg, PhD



Hall Gregg is a technology leader and advisor with 30 years of leadership experience in growing, scaling, and transforming global business in the life sciences industry with revenues ranging from \$5B to \$50B.

Having worked as an information technology executive for three leading pharmaceutical companies - Merck, Amgen and Pfizer, the largest blood bank in the United States American Red Cross, and the nation’s leading provider of laboratory diagnostic testing Quest Diagnostics, Hall possesses a unique set of experiences and leadership skills across multiple technology areas.

Highlights of Hall’s work include:

- Delivering digital, data automation and analytics strategies and solutions for internal company use and for customers,
- Leading large system standardization projects in regulated environments,
- Transforming global IT organizations and their culture to deliver greater value,
- Leading international revenue generating businesses with \$250M revenue,
- Serving on company leadership teams responsible for business transformation, supporting acquisitions and driving inclusion and diversity

Hall is an active member and former board member of the PRISME Forum. She is also on the board of Girls Inc. Of Chattanooga and a member of the advisory board at the University of Tennessee Chattanooga Rollins School of Business.

She lives in Chattanooga, Tennessee and is passionate about encouraging and supporting women in STEM and advancing the use of information technology in healthcare.

Dónal Landers, DPM, FFPM



Dónal Landers is Director of the digital Experimental Cancer Medicine Team at The Cancer Research UK Manchester Institute. The digital ECMT is a clinical decision science research group part of Cancer Research UK Manchester Institute. Its mission is to provide next generation patient cancer care through comprehensive data-driven evidence to enable the transformation of clinical decision-making, the evolution the role of the patient and the improvement of patient outcomes.

After obtaining his primary medical degree from Trinity College, Dublin, Dónal spent several years in practicing in medicine as a clinical research registrar in HIV medicine and Infectious Diseases. He undertook an MBA at University College Dublin before transitioning to hospital senior management at St. James's, an academic teaching hospital, in Dublin, where he led the clinical informatics group encompassing casemix and clinical performance improvement development whilst also extending into clinical and health informatics and computer science research (Dublin City University). Dónal later co-founded his own health informatics company developing patient 'centric' mobile technology solutions, which enabled patients to collect and monitor their own health data. After a number of years in various technology start-up companies, he joined PricewaterhouseCoopers as a specialist senior consultant and became sectoral lead for the healthcare and pharmaceutical industry. Dónal joined AstraZeneca in 2010 and took up a pharmaceutical physician role in Early Clinical Development (ECD).

He has recently worked as Senior Director Physician ECD and led AZ's first large multi-drug oncology 'umbrella' study in bladder cancer (BISCAY) before branching out to set up his own consulting business, DeLondra Oncology, specializing in early clinical and translational drug development in oncology.

Dónal is a specialist in Pharmaceutical Medicine and a Fellow of the Faculty of Pharmaceutical Medicine at the Royal College of Physicians and has fully completed his specialist training (CCT). He also holds a Postgraduate Certificate in Translational Medicine from the University of Manchester and is fully registered on the GMC specialist register. He is a member of ASCO and ESMO.

Amrik Mahal, PhD



Amrik Mahal is Head of Information Technology for Research at AstraZeneca. In this role he is accountable for developing and driving the IT strategy, partnering with R&D senior leaders and delivery all IT projects, services and capabilities to support target identification, drug discovery and preclinical. Though based in the UK he is currently on secondment in Gothenburg where is the Head of IT - Sweden.

Dr. Mahal is an accomplished scientific and informatics leader with 25 years of experience in the Pharmaceutical Industry. He started his career as a chemist at Glaxo Wellcome, Oxford Asymmetry, Evotec and has held numerous IT leadership roles in AstraZeneca in both Research and Clinical Development.

Diana McKenzie



Diana McKenzie is a technology executive, advisor, and board member with over thirty years of leadership experience gained from growing, scaling, and transforming global businesses in the Life Sciences and Software Industry with revenues ranging from \$3-20B.

As the former Chief Information Officer for Workday and Amgen, she serves on the boards of MetLife, Vertex Pharmaceuticals, Change Healthcare, Paradox and MindX Sciences and continues to expand her expertise in areas of digital strategy, talent development, enterprise risk and cybersecurity as a Special Advisor at Brighton Park Capital.

As the first CIO at Workday, a leading global cloud-based ERP software company, Diana built and led the IT and Security organization on a best-in-class journey to fuel the company's 30+% YOY growth while preserving their award-winning values and culture.

As CIO at Amgen, the world's largest biotechnology company and a member of the executive team, she led multiple

enterprise-wide work streams as part of the company's strategic transformation resulting in the implementation of innovative technology enabled operating models and streamlined business processes delivering returns exceeding \$1B.

Prior to joining Amgen, Diana served for 17 years at Eli Lilly and Company in a variety of IT leadership and cross functional roles. She serves on MetLife's Audit and Finance & Risk Committee, Change Healthcare's Compliance and Audit Committee and Vertex Pharmaceuticals' Nomination and Governance Committee. She has served as Co-Chair of the Ventura County Long Term Services Board of Directors and Co-Chair and founding board member of the Clinical Research Information Exchange. She remains active as an Advisor to World50's CIO community and volunteers philanthropically to grow membership in the communities of One Mind at Work and T200 CXO Women in Technology.

Diana is a thought leader and frequent speaker on digital transformation and diversity. She was recognized by the National Diversity Council in 2015 as one of the nation's Most Powerful Women in Technology and by the San Francisco Business Times on their Forever Influential Women's list. She was recognized by Purdue University's School of Technology as a distinguished Alumna in 2004.

Geralyn Miller



Geralyn Miller is a Senior Director on the AI for Good team at Microsoft where she focuses on Health Strategy. Prior to joining the philanthropies group at Microsoft, Geralyn led the Microsoft Genomics product team from inception to commercial availability in Azure.

Geralyn's career history includes shipping flagship software products for large enterprise companies. Geralyn's business acumen is supplemented with a deep technical knowledge base including work as a software developer and systems administrator on a variety of platforms using many software languages and tools.

Geralyn is a Time Magazine author on the topic of Artificial Intelligence in Healthcare and a speaker on the topic of health equity and AI.

David Neilson, MS



David Neilson leads R&D business engagement for IT at Gilead Sciences. He joined Gilead in 2014 and is based at the San Francisco HQ. Gilead is going through a corporate business transition and David is engaged in various initiatives, in aligning technology investments to strategic and evolving R&D business capabilities.

Prior to Gilead, David spent 12 years at Johnson & Johnson in various IT roles supporting Research and then as head of IT for a group of J&J biotechs and in one case, head of IT for a joint venture.

After completing a Master's degree at Edinburgh University, David worked 10 years in France heading up IT for Research, first at Synthelabo and then Sanofi.

Marina Perrin



Marina serves as the Senior Director of Strategic Accounts managing several of Science 37's key accounts. Marina has more than 16 years of experience in strategic planning, clinical information systems management, and developing and fostering partnerships and alliances across a range of therapeutic areas and companies including Genentech, Roche, Biomarin Pharmaceuticals, and Audentes Therapeutics.

Prior to joining Science 37, Marina was Director of Development Operations at Audentes Therapeutics. In this role Marina led project teams to deliver the company's first first-ever interventional AAV gene therapy clinical trials for X-linked Myotubular Myopathy and Crigler Najjar Syndrome. Marina holds a BA from Bryn Mawr College.

Jaydev Thakkar



Jaydev Thakkar is currently Chief Operating Officer at Biofourmis. Biofourmis is a digital therapeutics company founded in 2015 with the vision to empower personalized predictive care by delivering precise interventions at the right time to improve outcomes. Biofourmis solutions are deployed world-wide with some of the world's most respected healthcare providers, ministries of health and pharmaceutical companies—collaborators like Novartis, Chugai, Brigham and Women's Hospital, and Mayo Clinic.

Prior to Biofourmis, Jaydev was with Amgen for 14 years, where he led its "beyond the therapy" digital innovation strategy to maximize product value and clinical outcomes across the patient journey—from clinical development through product launch and post-marketing—in partnership with cross-functional product leadership teams. At Amgen, Jaydev also led information technology groups for the company's large portfolio of global clinical trials—including some of the largest ever in the industry, with more than 27,000 participants across 50 countries and more than 1,000 sites.

Before Amgen, Jaydev was a telecommunications, technology and finance consultant who co-founded a technology startup and also managed his family's manufacturing business.

Ed Tourtellotte



Ed Tourtellotte, 4G Clinical CTO, was the founder of Tourtellotte Solutions, a clinical trials consulting and technology company (acquired by Bioclinica).

Ed designed and built the world's first configurable IRT in 2000, and also designed the clinical trial supply simulator tcVisualize as well as Trident IWR. Ed has a knack for discovering, attracting, and retaining incredibly talented teams, and is a frequent speaker at clinical technology conferences.

Ed has a BA in Economics from Duke University.