



CSS 2021

The Computational Science Symposium

September 13th–15th

PHUSE/FDA Innovation Challenge “Prime the Pump”

Chris Hurley
PHUSE
Americas Director

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Agenda – Three P's

- Planning
 - Today's breakout sessions
 - Roadmap
 - Timelines
- Partners
- Pillars



Today's Innovation Challenge Sessions



Introductory Session	<ul style="list-style-type: none">• The Seven Pillars
Design Thinking – BYOI <i>“Bring Your Own Ideas”</i>	<ul style="list-style-type: none">• Develop the three problem statements for the Challenge• Design Thinking – How we collaborate
Rules & Delivery – BYOC <i>“Bring Your Own Challenge”</i>	<ul style="list-style-type: none">• You will help shape the rules of engagement for the challenge
Session Leads	<ul style="list-style-type: none">• Vannessa Williams, FDA• Gayathri Kolandaivelu, Janssen Research & Development



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**Working
Groups**

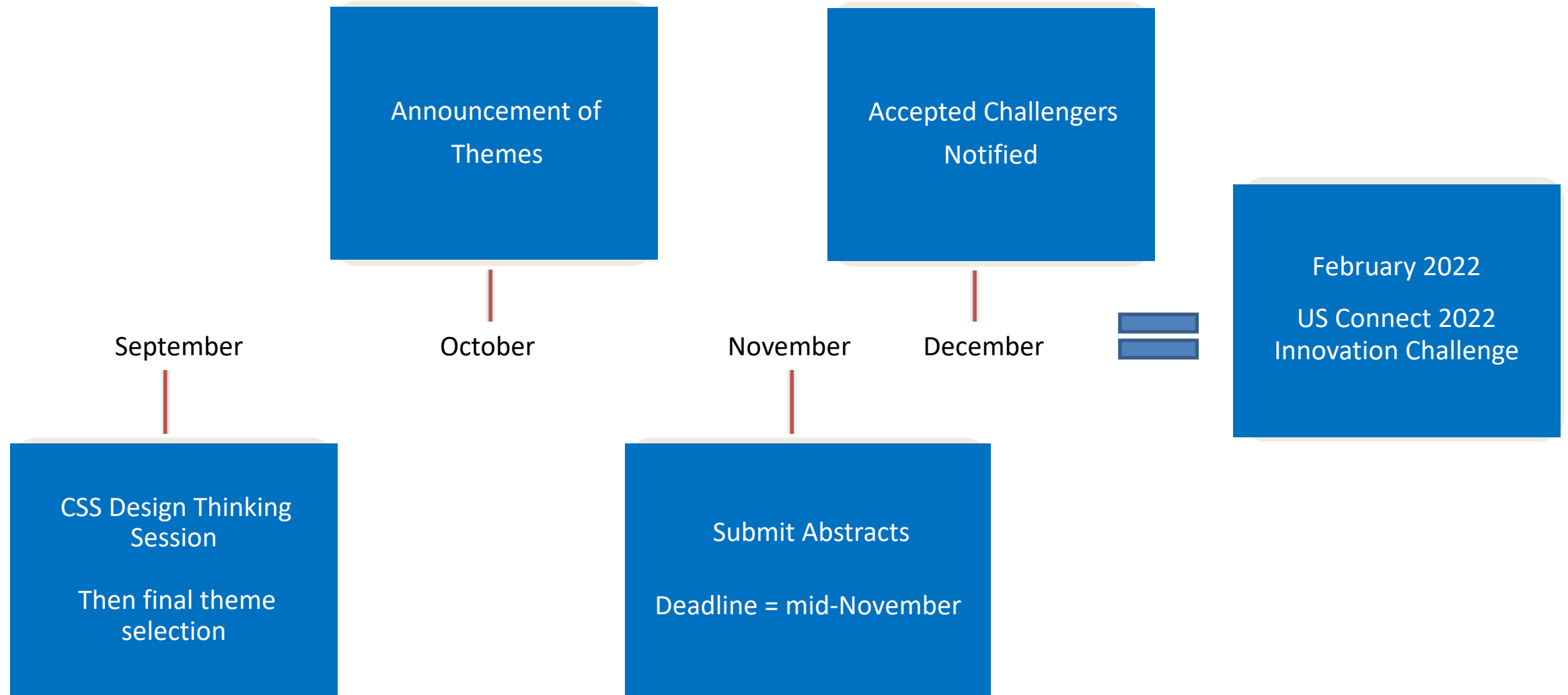
Roadmap to Atlanta



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**Working
Groups**

Timelines



PHUSE/FDA Innovation Challenge Partners



Lilliam Rosario
Director
Office of Computational Science, CDER

PHUSE/FDA Innovation Challenge Partners

Microsoft

- Technology partner for past 2 years
 - PHUSE Education Team / Azure credits / PODR
- Brings experience with hackathons and Innovation Challenges
 - NurseHack4Health (J&JJ, 600 participants)
 - Hack for Equity in partnership with J&J (250 participants)
- How they may help us after the CSS as we move forward
 - Hosting data
 - Mentor/educate teams on AI/ML/PowerBI
 - Provide platform like Teams for a community feel/experience

PHUSE/FDA Innovation Challenge Partners

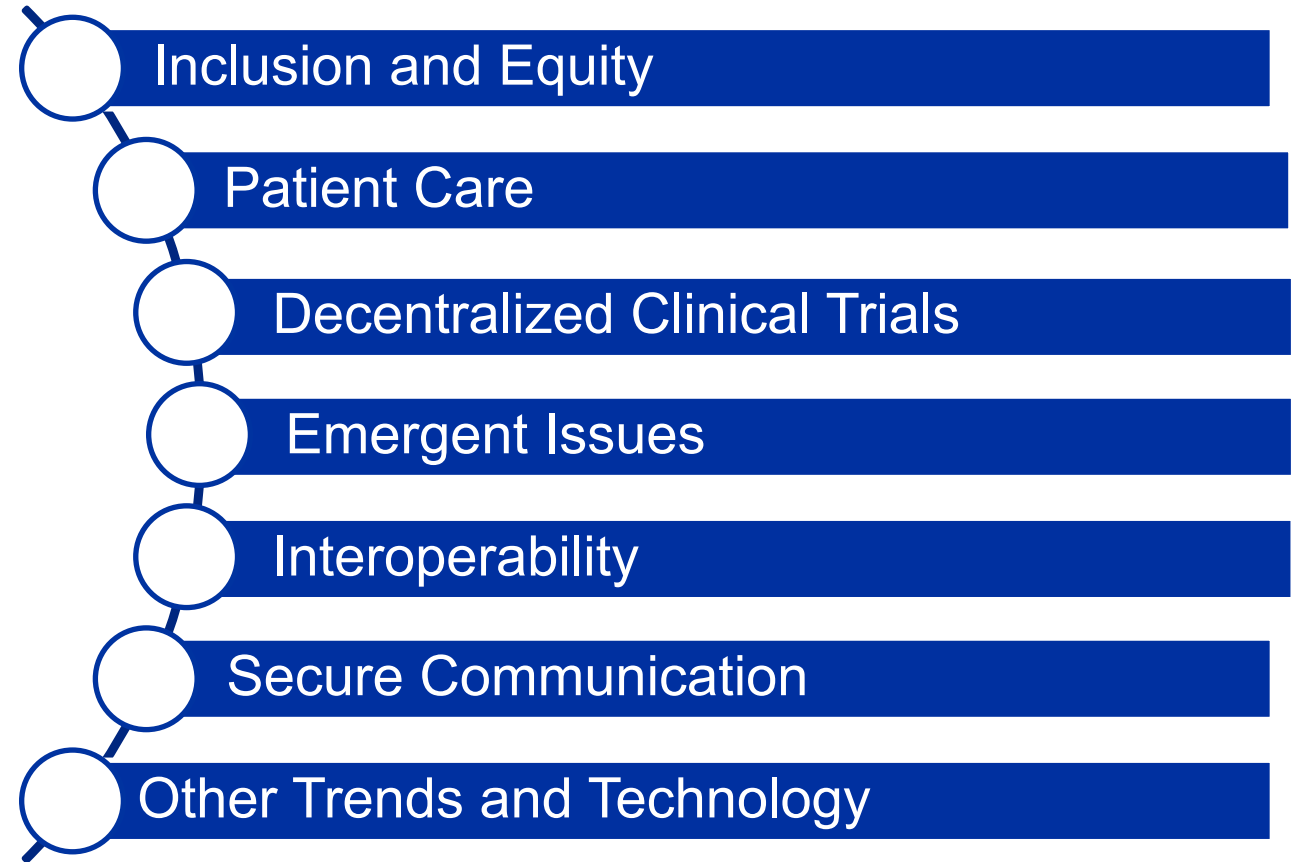


A research and policy center focused on addressing the conduct, oversight, ethics and regulatory environment for clinical trials.



Barbara E Bierer
Faculty Director
Professor of Medicine, Harvard Medical School

Pillars to Prime the Pump



Pillars to Prime the Pump

Inclusion and Equity

This pillar focuses on engaging stakeholders and trial participants in emerging economies and diverse communities while implementing ethical, practical and actionable ideas for inclusion and equity in clinical research.

Pillars to Prime the Pump

Patient Care

Enable Clinical Research as a Care Option (CRAACO) care teams to find ways to successfully identify, select and integrate clinical research opportunities within the patient care continuum for chronic or rare diseases.

Pillars to Prime the Pump

Decentralized Clinical Trials

Overcome the obstacles constraining the facilitation of diversity, better patient experience, better methods and acceleration to market.

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Emergent Issues

COVID-19, the opioid crisis, drug-drug interactions and other issues facing our industry.

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Interoperability

Standards such as CDISC, HL7, FHIR enabling automation and connecting Real-World, provider and payer data to clinical research.

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Secure Communication

Collaboration and data sharing with an emphasis on how to train and understand messaging to combat misinformation and build trust and efficiency with your data.

For example, potential regulatory and other use cases for implementation of immutable sources like blockchain, which may give general confidence in the security integrity and privacy of information.

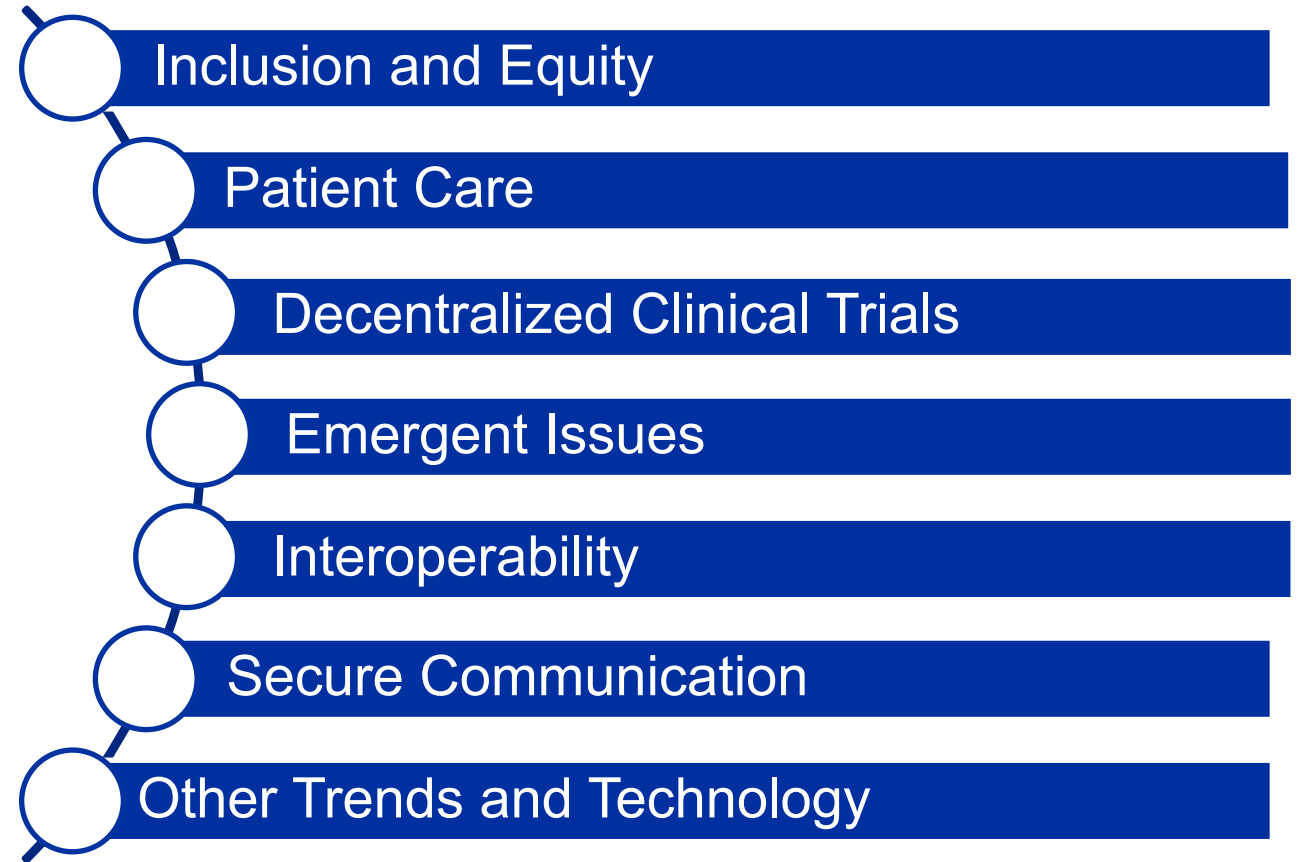


Pillars to Prime the Pump

Other Trends and Technology

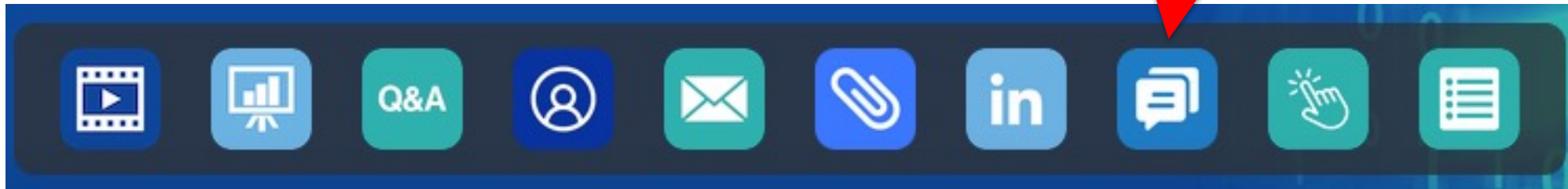
Utilizing mobile apps, QR codes, devices and other technologies in clinical research to facilitate new methods in data collection and analysis.

Pillars Not Mutually Exclusive



Feedback – Your Ideas

Please use the group chat to enter any other ideas to be considered for challenge themes.



Thank you!



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Groups**

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Breakout sessions will begin at 13:30

PLATFORM CONTRIBUTOR

IBM