



Real-world Evidence and Regulatory Submissions

David Hood

What is the point?

Bringing life changing medicines to patients

Regulations don't call for RCT

COVID19 highlights opportunities to be more



Agile in our response

Flexible as a system

Personalized

What's been done before?



Regulatory

- HIPAA
- 21st Century Cures Act
- Unified
- Methodical



Business

- Pharma
- Insurance
- Targeted
- Sustainable
- Ad Hoc
- Silos



Open Source

- PHUSE
- OHDSI
- Collaborative
- Vary approaches
- Duplicate efforts
- Varied goals

We are living through the digital disruption of the pharmaceutical industry but it doesn't look like other disruptions

How our attempt differs

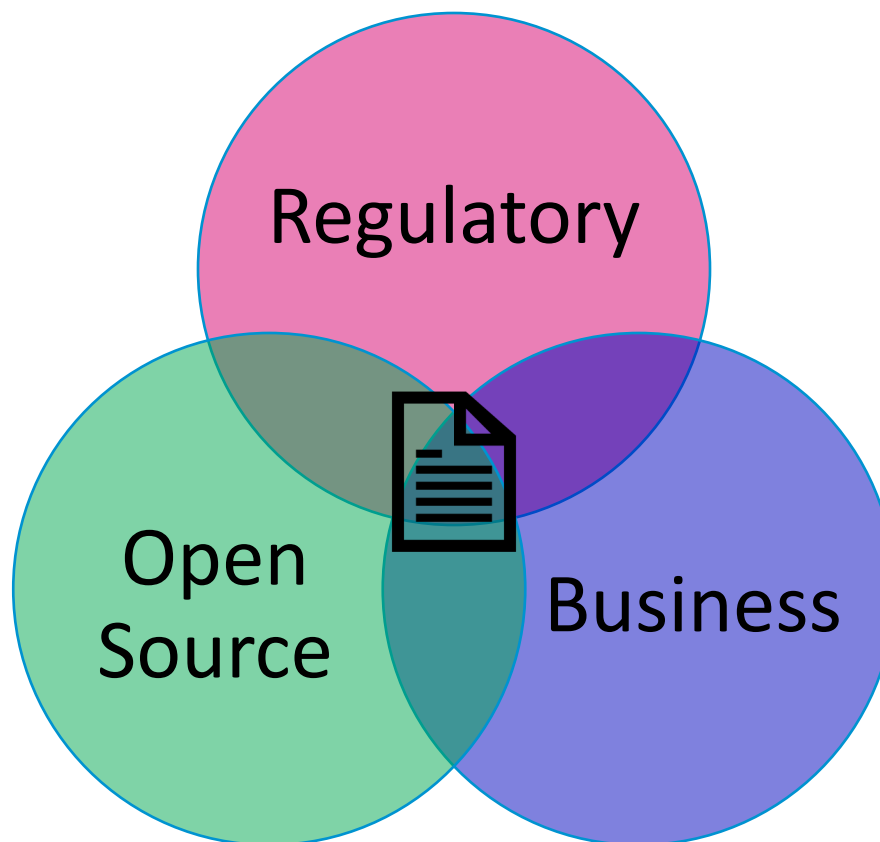
Thank you!

Andy Richardson
Lauren and PHUSE team

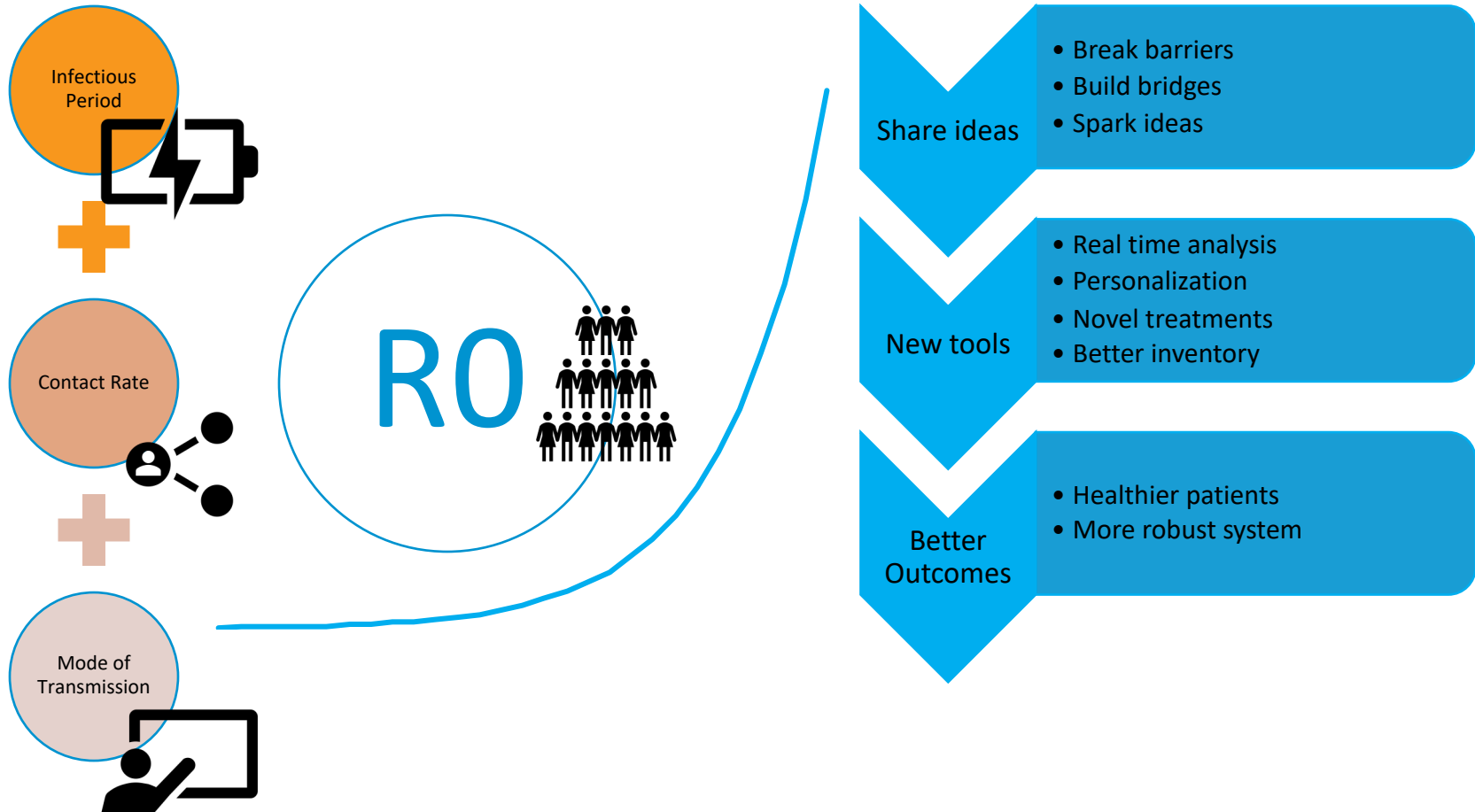
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Why does this matter?



Break the curve

