Global Advancements in Clinical Trials

Presented By: Shilpakala Vasudevan

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Why Innovation?

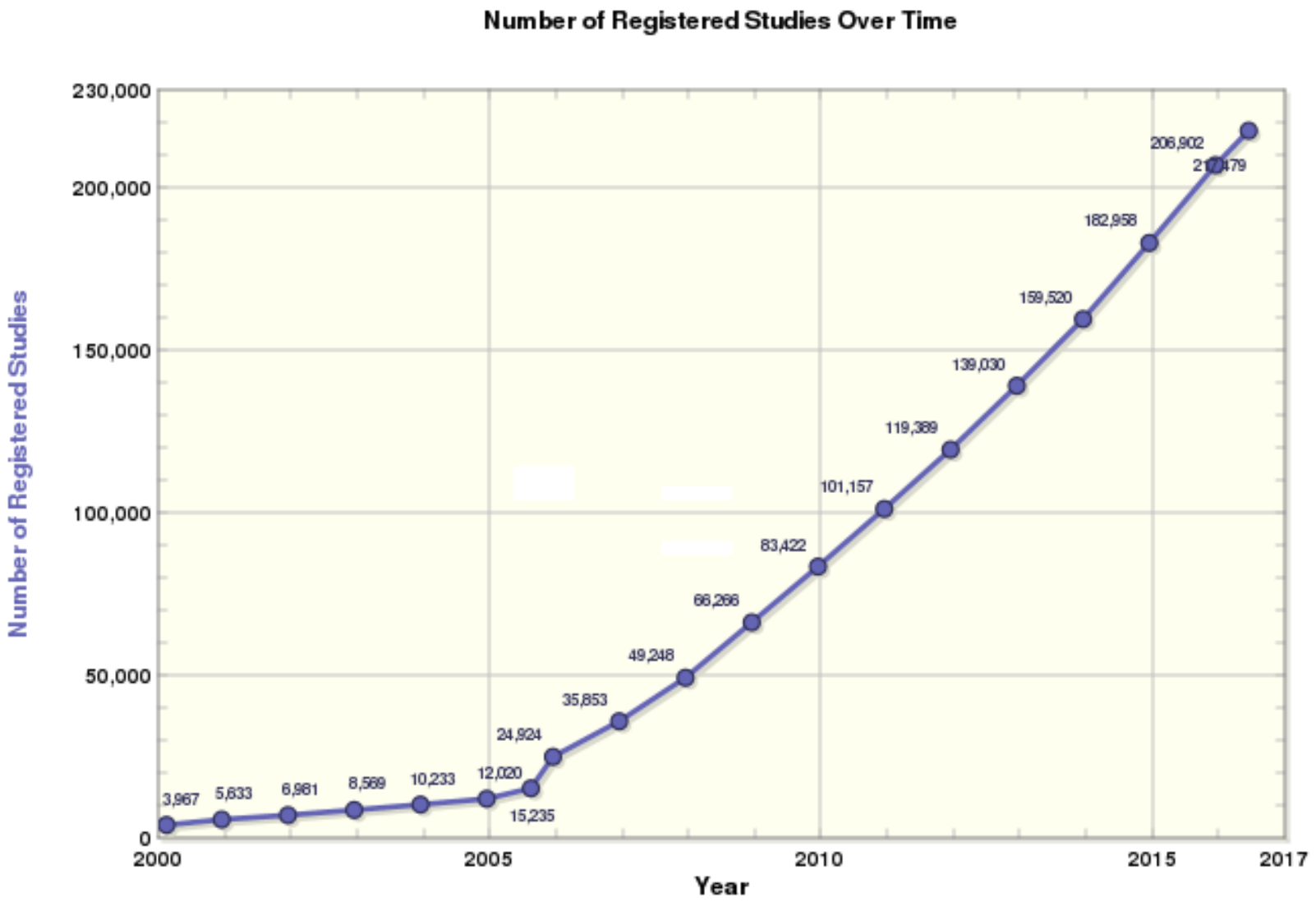
Patient Safety

Data Quality

Faster Timelines

Lower Costs

Clinical Trials Trends



Areas of advancements

- Patient Recruitment
- Site Selection
- Data Integration
- Existing Data Sources
- Mobile Tech
- Project Management
- Risk-Based Monitoring
- Clinical Auditing
- Quality (QbD) in Trial Conduct
- Outsourcing
- Vendor Management
- Budgeting and Contracting

Patient Centricity

Patient Centric

Conducting and providing measurements directly from and by the patients in their homes

Mount Sinai Health System – medical assessments conducted remotely through telerobotics

Site Centric

Conducting study visits in local neighborhood clinics and centres and remotely monitoring through telehealth

Novartis partnered with Walgreens to run a 10,000 patient clinical trial plot

Patient Centricity

Pros

- More convenience for patients
- Reduce trial visit costs
- Reduce travel burden
- Less subject drop outs
- Improve patient and investigator interactions
- Work best with less complex clinical trials and easy data collection methods

- Investigator less in control over their patient and more accountable
- Patient may not adhere to study regiments affecting data quality
- Patients could be less satisfied with their participation
- Difficult for complex procedures
- Less revenue for sites

Cons

Patient enrolment

- TrialReach

  - Statistical, probability and machine learning algorithms, in combination with patient networks.

  - Referral Management Service

Patients to engage in clinical research *before* they have to travel to the site.

Patient engagement

- Optimal Strategix Group (OSG)

CAVII Mobile Application

Patient behavioural, medical, and patient reported outcomes collected, aggregated, quantified and categorized into patient engagement profiles.

Diabetes Urgency Index	0.3	0.4	0.6	0.75
Patient Needs	I need to control diabetes and not let it control me - More Energy - Feeling of control - Enjoy doing what's right - Feeling engaged and optimistic	I need to use knowledge and discipline to get the most out of my life - More knowledgeable - - Less worry - - More active, social - Eat out with family and friends	I need to find a way to protect myself from diabetes - Avoid complications - Feel better about my body - Win the food battle	I need help controlling my health and diabetes - Avoid insulin and long term complications - Understand what I need to do
Patient Attitudes	Focused, Do What They Are Supposed To Do - Involved - Willing to make lifestyle changes	Sensible - Work on limiting carbs and sugar - Realize that they may never get off medication	Worried - Find lifestyle changes to be hard - - Worried that diabetes will get worse with time	Fearful, Desperate - Live in fear of going on insulin - Feel that they will never get off medication
Patient Behavior	Follow the rules, do what the doctor says	Stick with that works, follow the routine	Trying to do what I have been told, but don't feel it is working	Struggling, seeking information, Trying to contribute to discussions with doctor
HbA1C score range	5.0-6.0	6.0-7.0	6.5-7.5	7.5-

Mobile Technologies (mHealth)

- Easily worn biosensors

  Fitbit

  Garmin's Vivofit

  Apple's iWatch

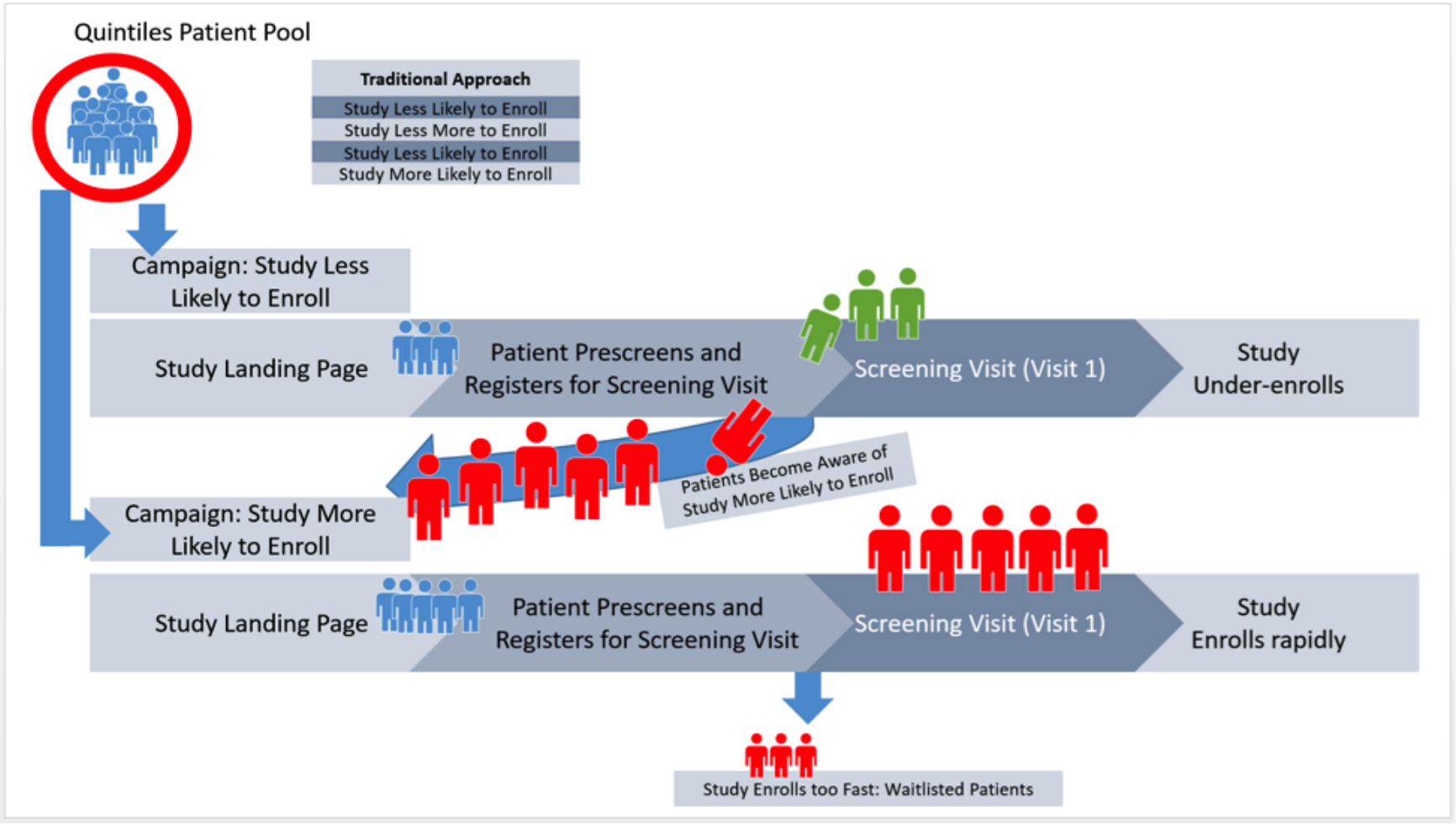
  Scanadu

  Spire

  Lumolift

Text Messaging

- Quintiles Phase I Unit



Text Messaging

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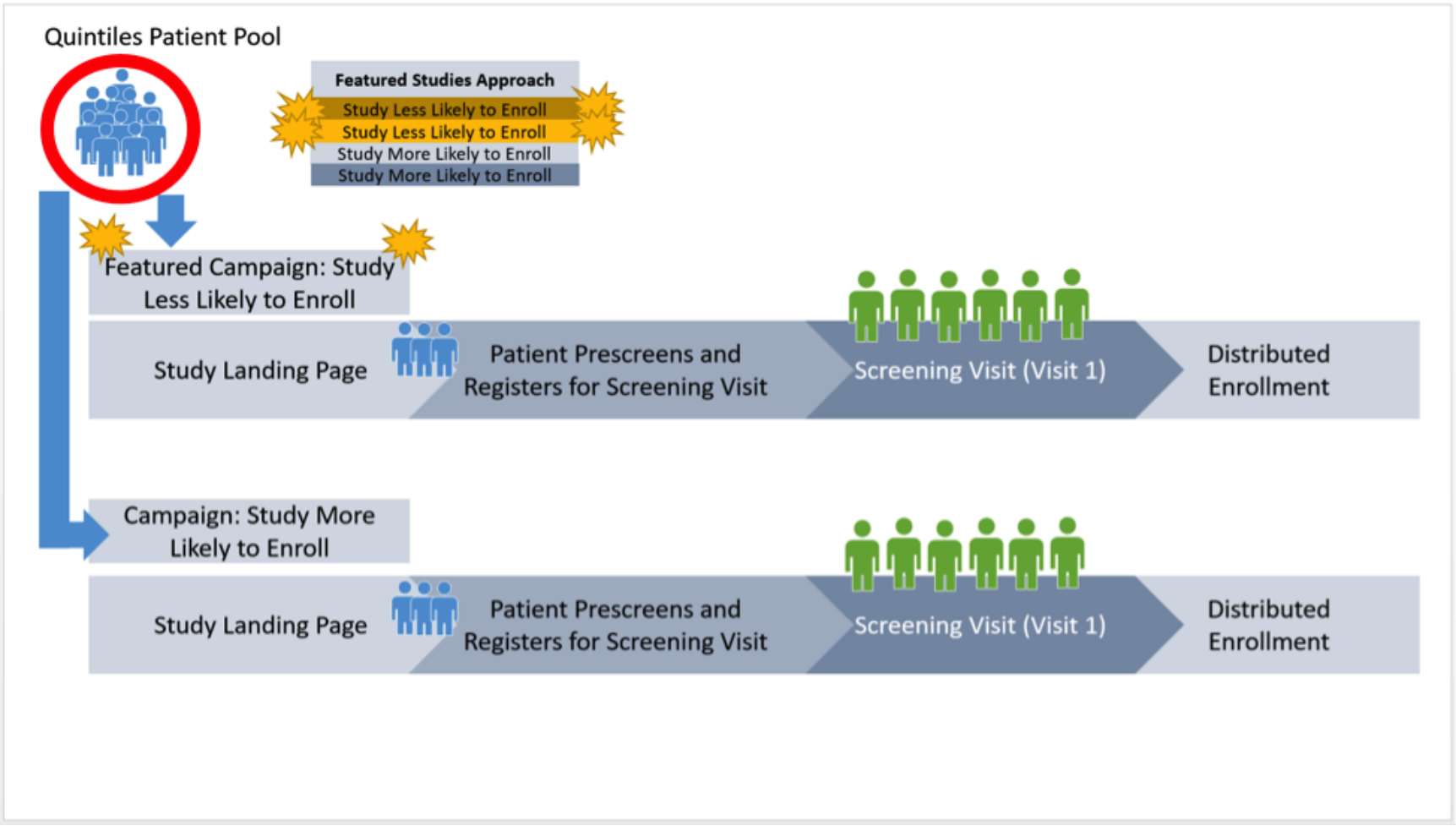

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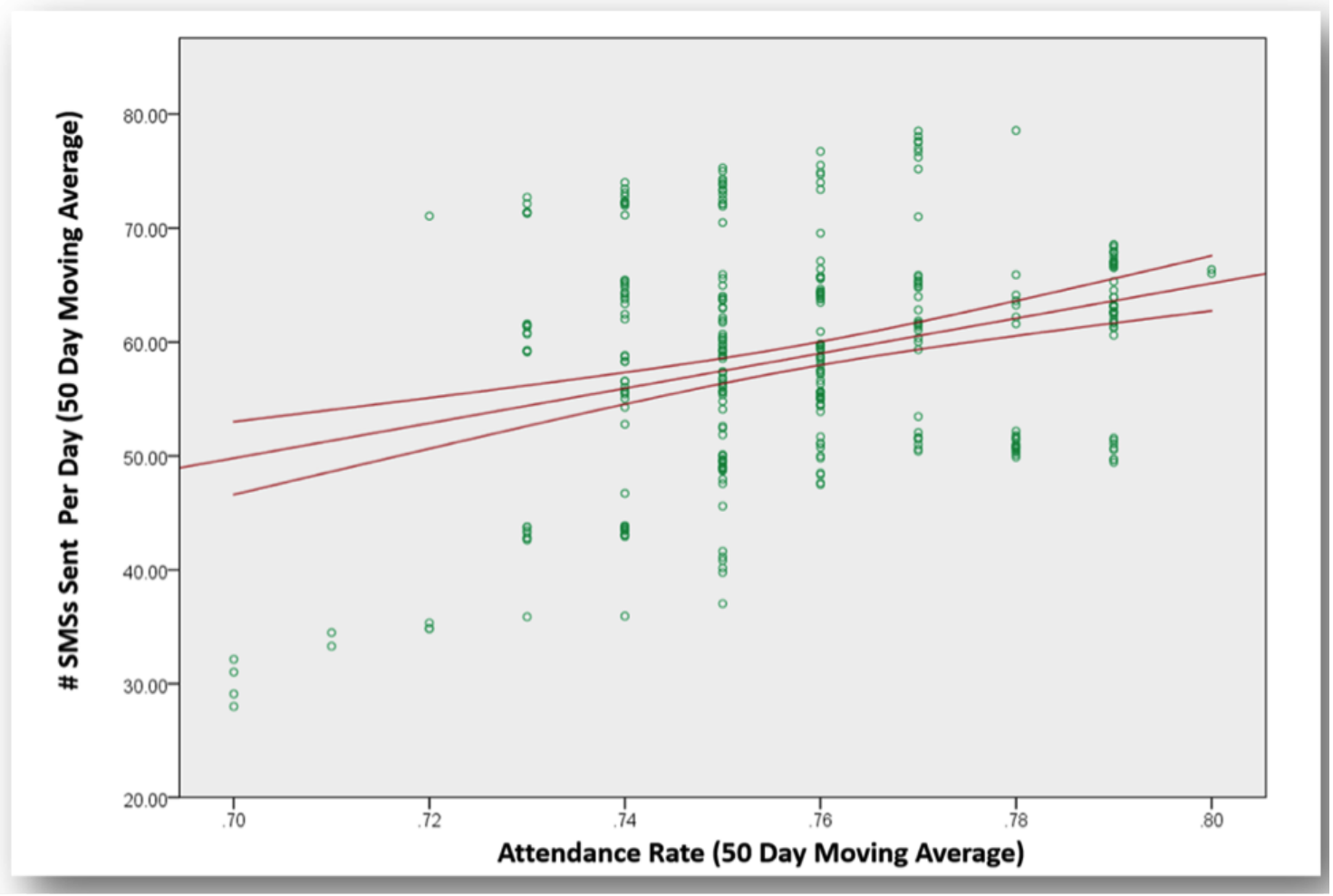

Risk based monitoring

Evolution of TransCelerate Methodology for Risk-Based Monitoring

CURRENT	PROPOSED	VISION
100% SDV / sampling	Risk-based, critical data focus	Analytics
On-site	Off-site + targeted On-site	Centralized

The IQRMP including the RACT, Critical Data, Risk Indicators, and Various Functional Plans

Risk based monitoring

- Many companies incorporating RBM
- RBQM (Risk based Quality Management) framework
- Quality Management System

Addendum to ICH GCP (E6)

- Addendum E6 (R2) to take effect this year.
- Fully embraces the quality-by-design and risk-based approaches. Monitoring and quality management are now to become truly risk-based.

What is to come?

- Patient Centricity
- Site selection technologies that leverage big data
- Emergence of endpoint adjudication software to establish endpoint adjudication guidelines
- Non-profit organizations introducing more collaborative initiatives (Transcelerate, ACRES, CTTI)
- Outsourcing of clinical trial services

Challenges

- Reluctance to forgo previous practices
- Need for more openness and be open to change
- No innovation departments in many enterprises

"This really is an innovative approach, but I'm afraid we can't consider it. It's never been done before."

THANK YOU