



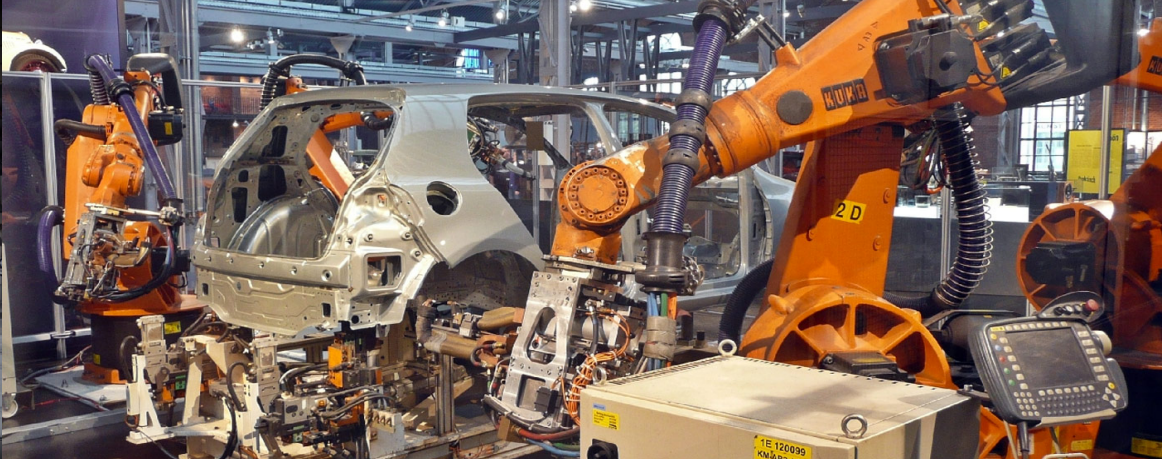
Clinical Trial of the Future: Technology-Driven Innovation in Clinical Research

David Hall



Acknowledgements

- Jeff Abolafia
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- Karen Kesler
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- Derek Lawrence
- Christopher Lyu
- Smitha Ragannagari



- ❖ High Stakes/High Cost of Failure
- ❖ Real and Perceived Regulatory Hurdles



- ❖ Technology
- ❖ Drug Development Challenges

Clinical Trials Innovation

Presentation Content

Overview

- Tech-Driven Trends
- Enablers/Drivers

Assess Industry

- Live Poll

Presentation Scope

Digital technologies

Used in trials

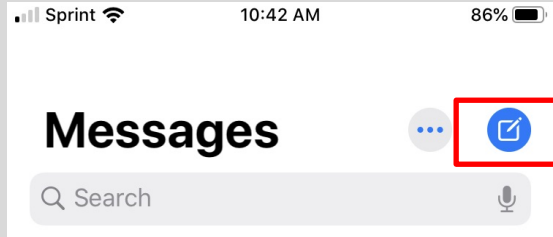
Applicable across therapeutic areas

Widespread adoption feasible

Emerging tech/emerging applications

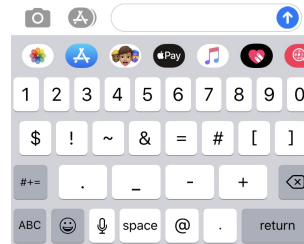
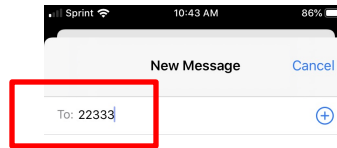
Step 1

Click icon to create new text message



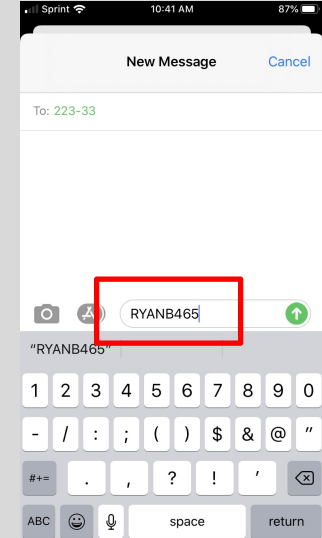
Step 2

Type **22333** in the **To:** line



Step 3

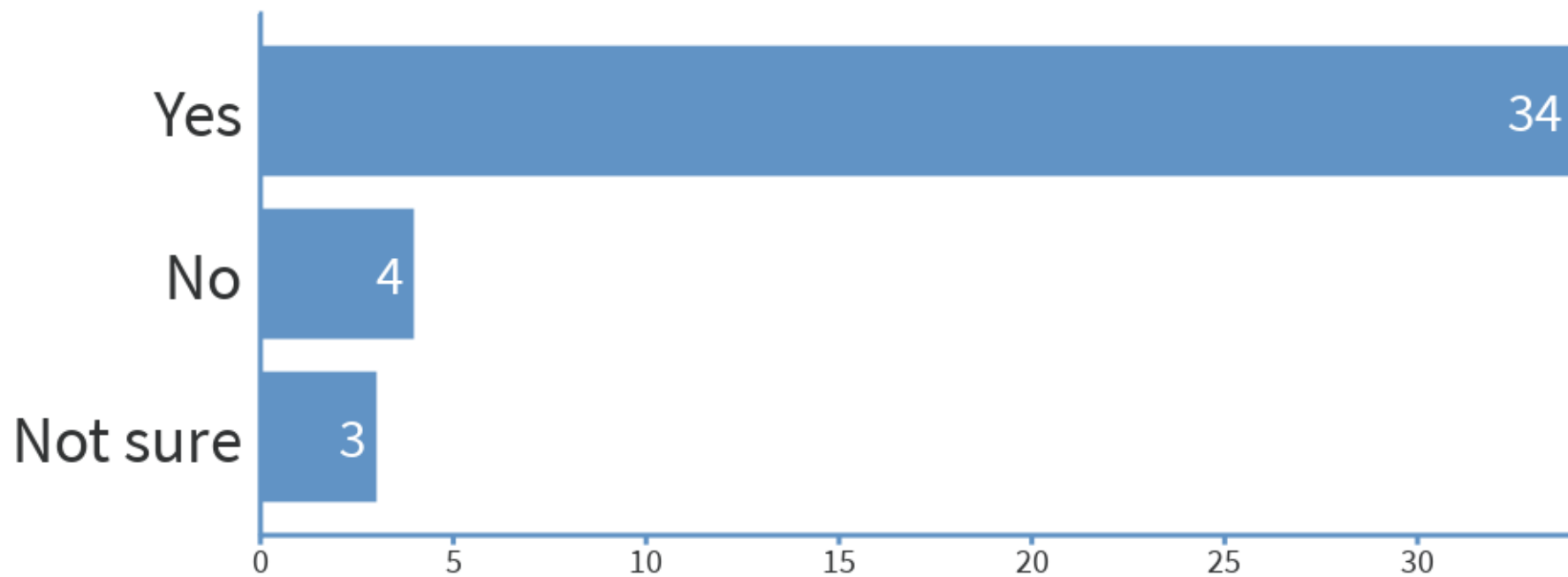
Type **RYANB465** in the message body and send





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Do you think that clinical research is entering a period of more rapid innovation?



Fundamental Tech Drivers



Computing
Power



Artificial
Intelligence



Mobilization



Connectivity



Miniaturization



Sensing

Regulators



Guidance for Industry

Electronic Source Data in
Clinical Investigations



Proposed Regulatory Framework for Modifications
to Artificial Intelligence/Machine Learning (AI/ML)-
Based Software as a Medical Device (SaMD)

Discussion Paper and Request for Feedback

FDA STATEMENT

**Statement by FDA Commissioner Scott
Gottlieb, M.D., on new strategies to modernize
clinical trials to advance precision medicine,
patient protections and more efficient product
development**



Drug Development Challenges



Current drug development costs around \$2 bn

Cost to develop a drug has doubled every 9 years since 1950s

70% of trials do not meet enrollment goals

30% of subjects drop out of trial on average

Clinical trial population often does not reflect overall population

Major Impacts



Design and
Planning



Ease of
Participation



Monitoring



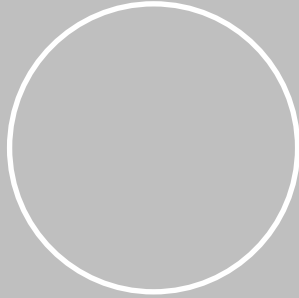
More and
Better Data



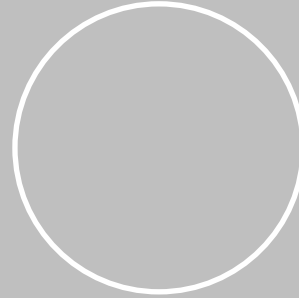
Major Impacts



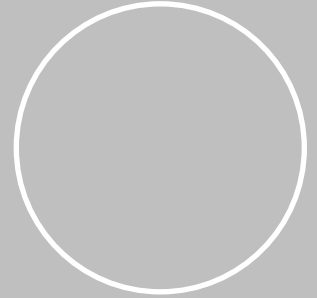
Design and
Planning



Ease of
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More and
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Design and Planning

Real World Evidence

- Feasibility
- Inclusion/Exclusion
- Finding Subjects

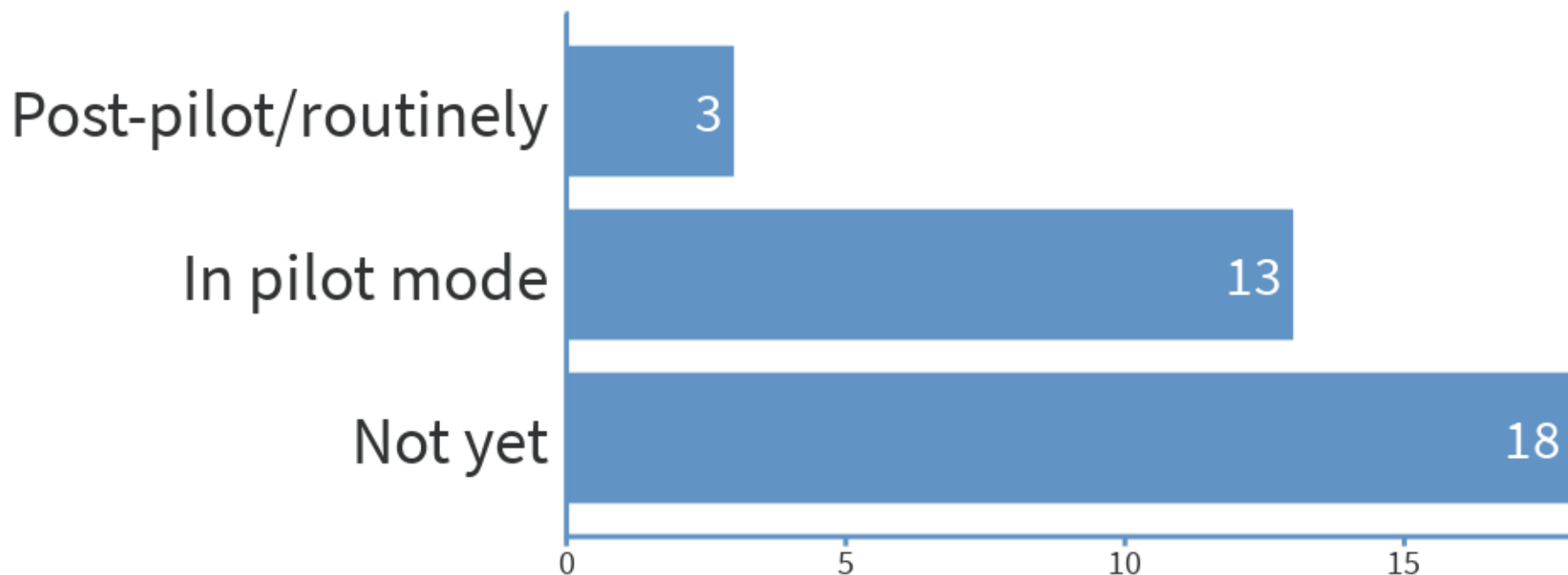
Artificial Intelligence

- Protocol Development
- Trial Simulation
- Site Selection



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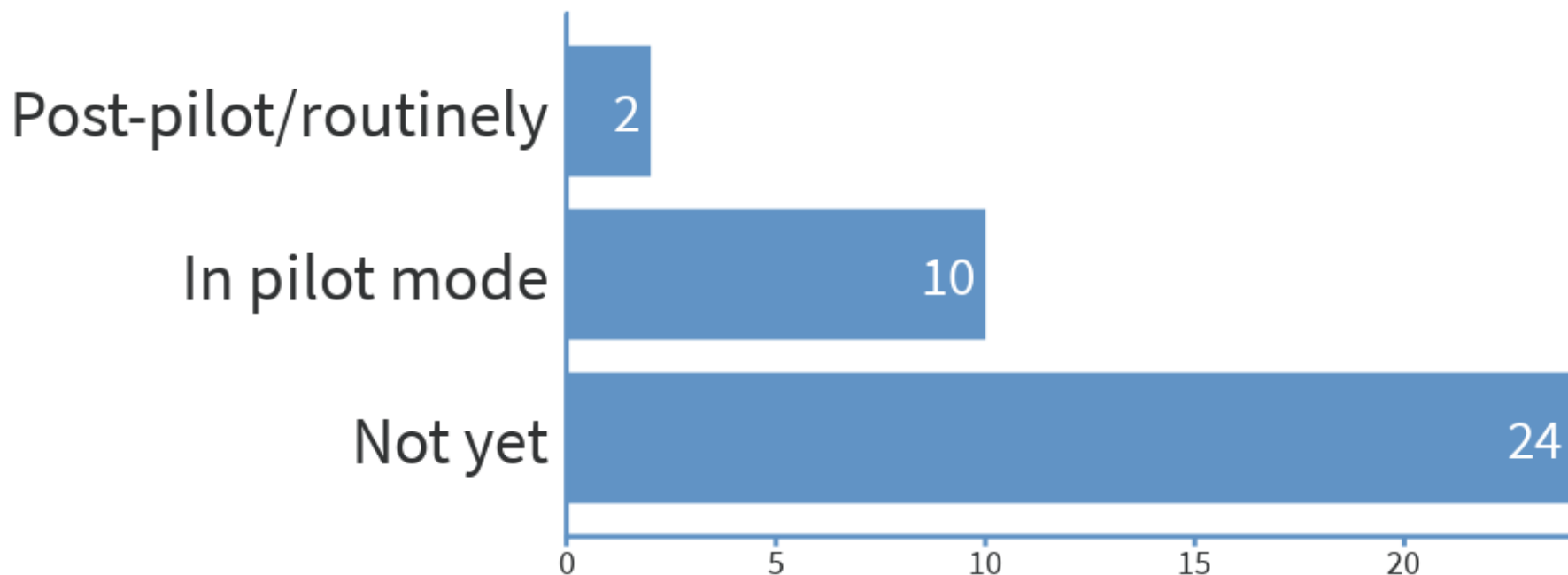
My organization uses Real World Evidence to assess feasibility, inclusion/exclusion, or find patients





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My organization uses Artificial Intelligence-based tools or techniques in the design and planning of trials



Major Impacts



Ease of Participation



eConsent



eCOA



Sensor Devices

- Wearable
- Portable



Alt Lab Testing

- Home Assays/Sampling
- Pharmacy
- Primary Physician
- Mobile Lab



Telemedicine

Virtual
Decentralized
Siteless Trials
Digital
Hybrid



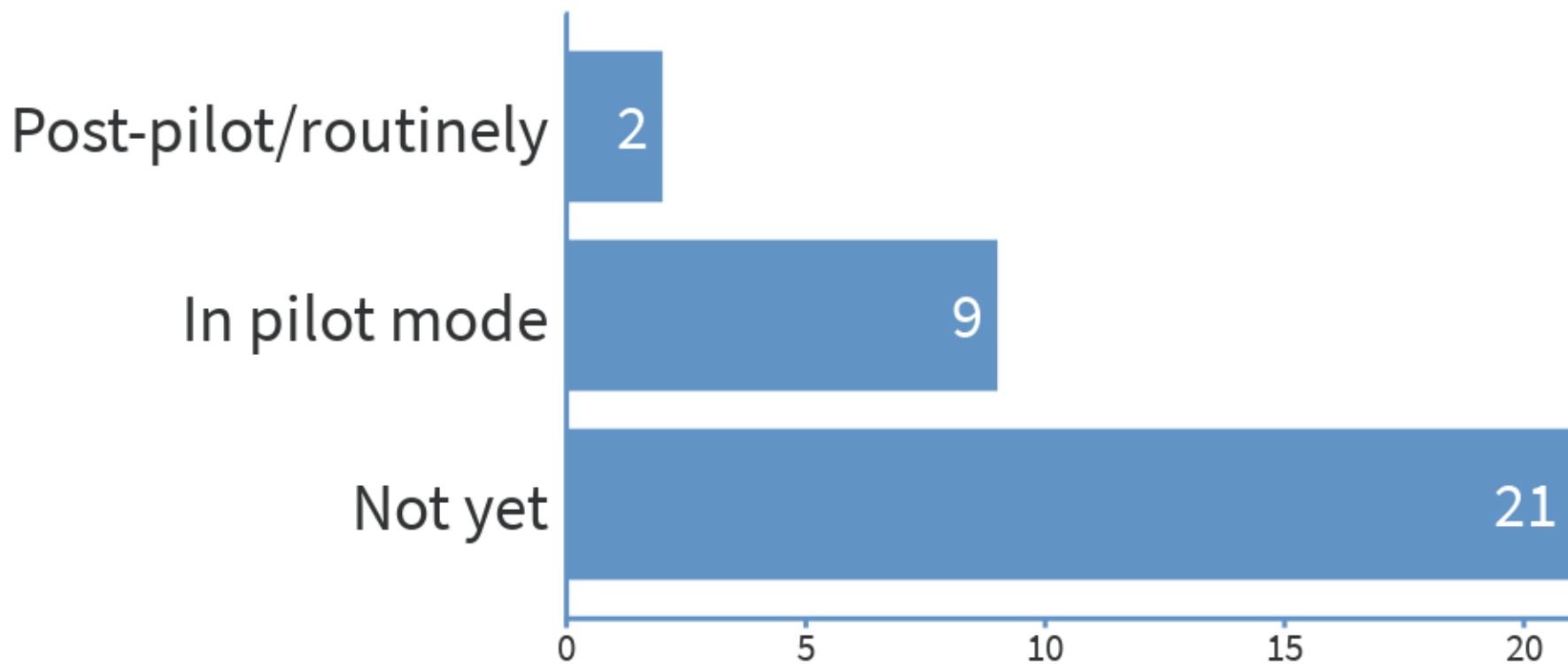
Recruitment
Retention
Geography
Patient-Centricity



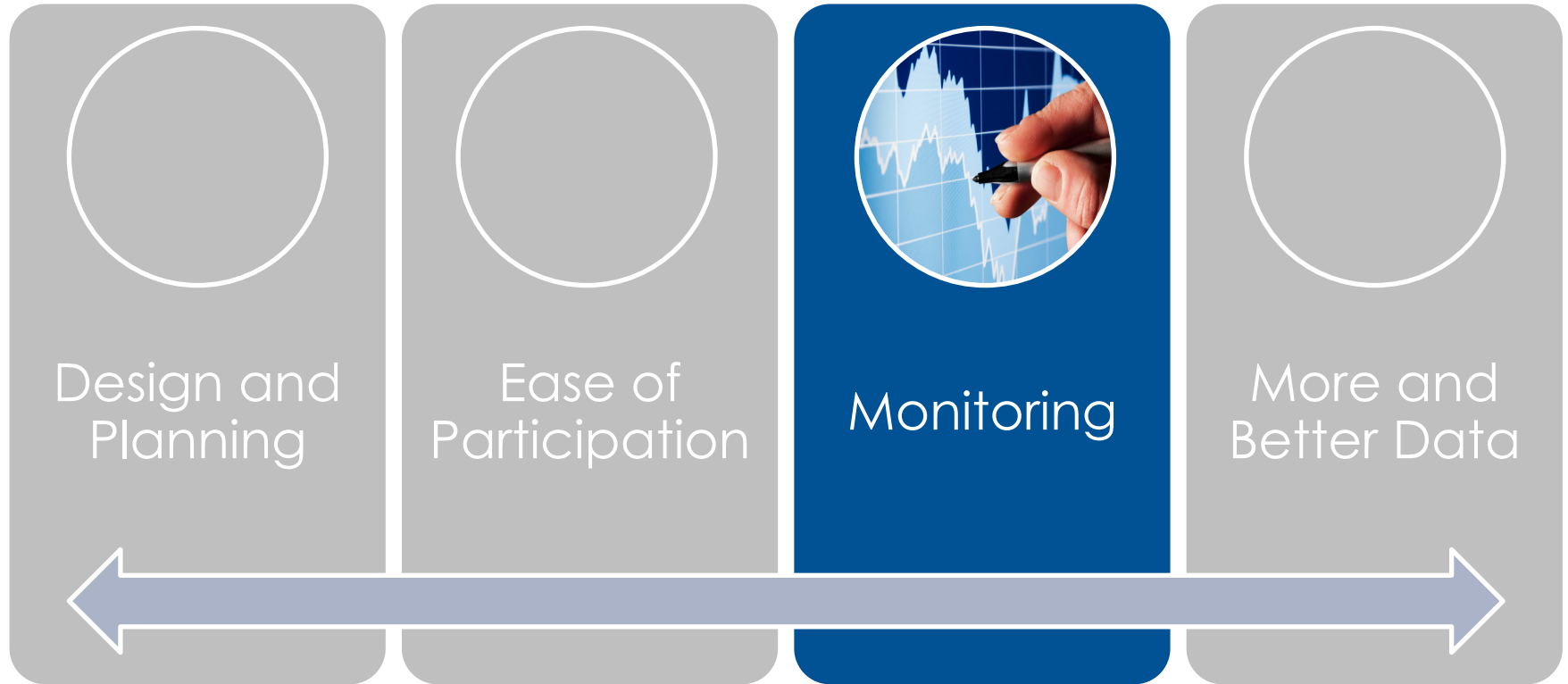


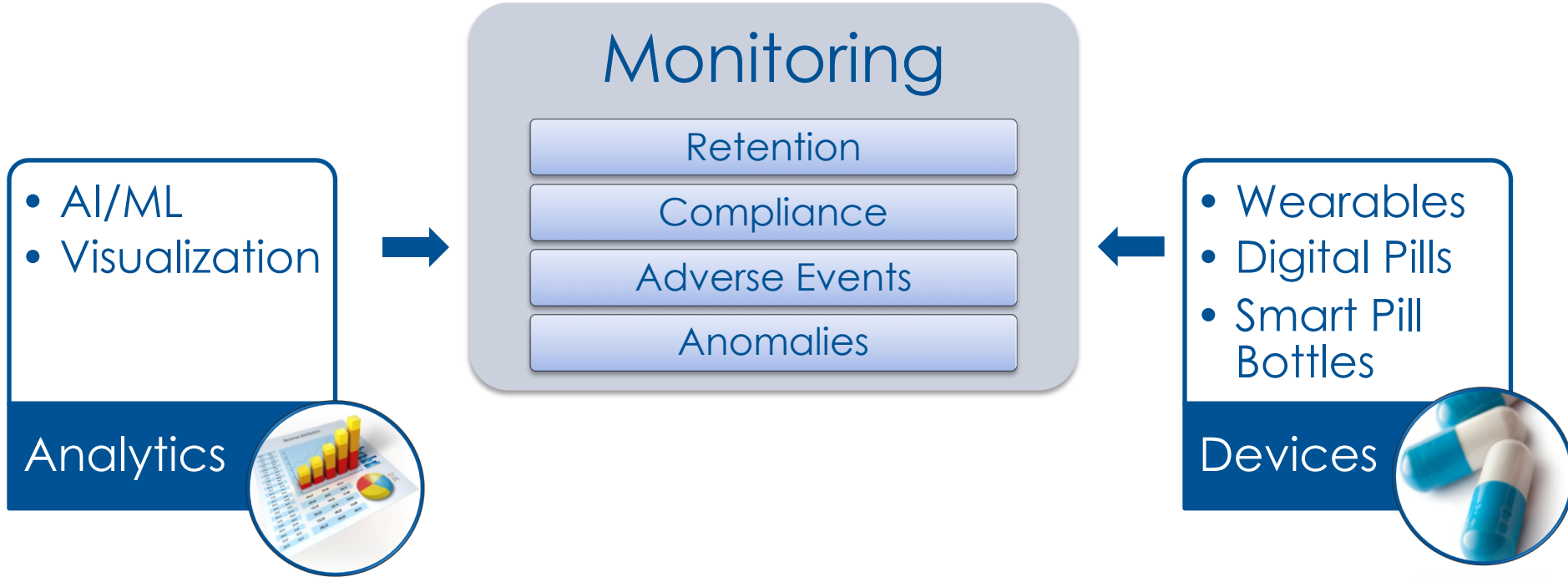
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My organization conducts Virtual or Hybrid trials



Major Impacts

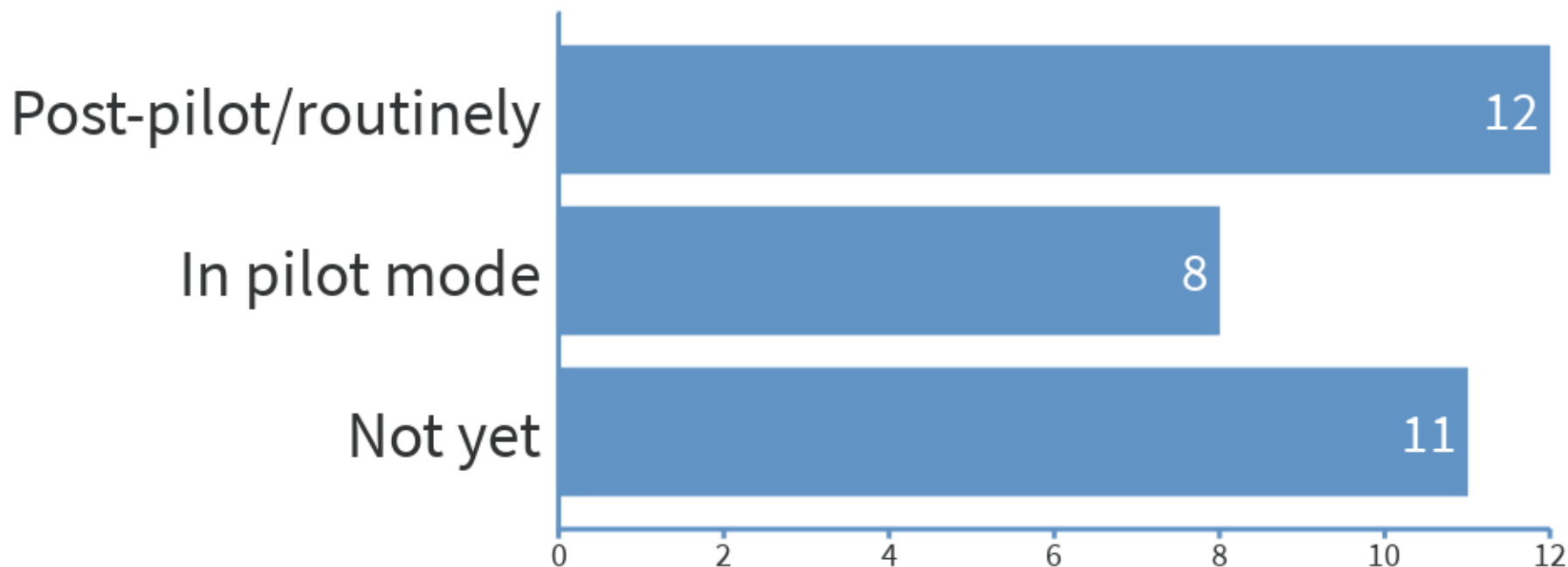






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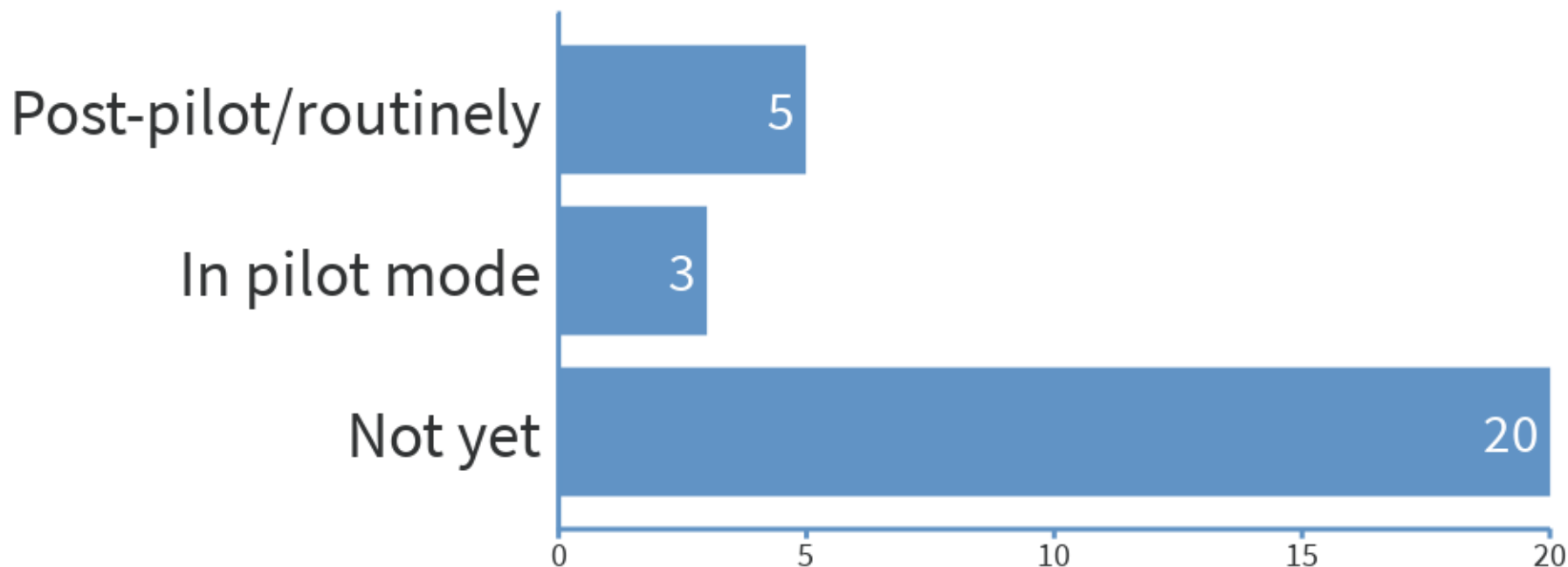
My organization uses analytic software to centrally monitor trials





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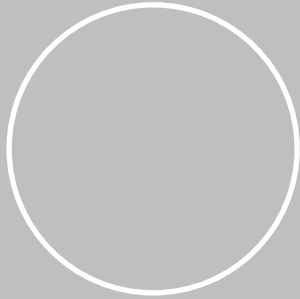
My organization uses technology to monitor adherence/compliance (exclude self-reporting)



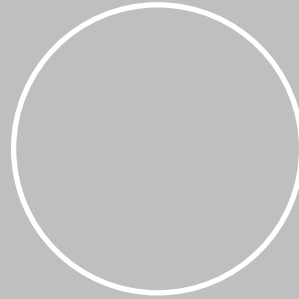
Major Impacts



Design and
Planning



Ease of
Participation



Monitoring



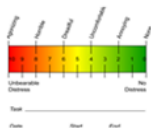
More and
Better Data



More and Better Data



Forms



Subjective



Qualitative



Clinic



Snapshot



eSource



Objective



Quantitative



Everyday Life

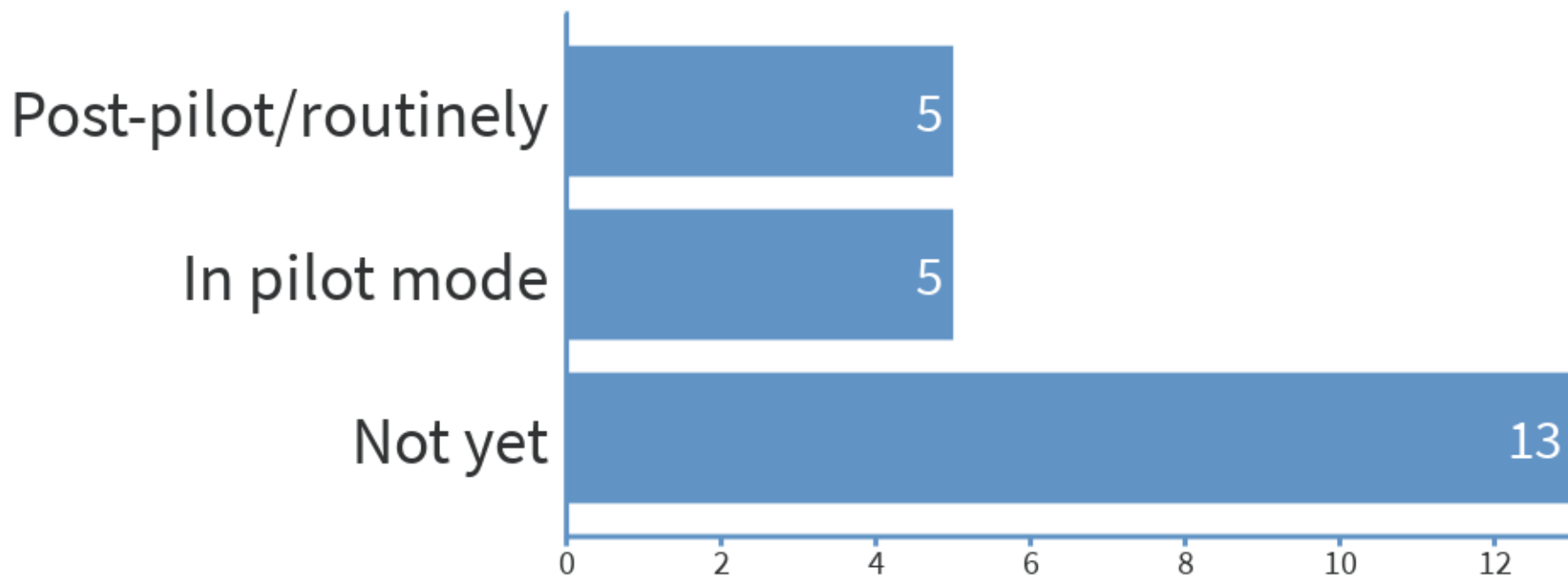


Continuous



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My organization utilizes Digital Biomarkers in clinical trials



What roadblocks does my organization face in implementation of technology-driven innovations in clinical research?



We tend to overestimate the effect of a technology in the short run and underestimate the effect in the long run

-Roy Amara

