

Digital in Trials: Improving Participation and Enabling Novel Endpoints

NIH Collaboratory Ground Rounds
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DISCLOSURE



Board of Directors



Board of Directors



Board of Directors



Mentor



Former employee
Shareholder

The opinions expressed are those of the presenter and do not necessarily represent employers or other affiliations.

With what other industry
could clinical researchers
benchmark themselves?

Research Sponsor's Outward Perception



Research Participant's Inward Perception





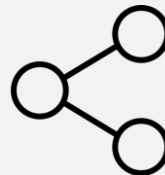
Clinical Trials : Airline Travel



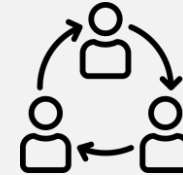
No one *wants* to be there, they just want to get to their *destination*



Information online often coming from aggregators with much less content



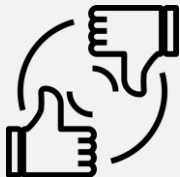
Execution relies on significant amount of *shared infrastructure*



Experience shaped by many people not directly employed by the sponsor



Each instance generates tremendous amounts of diverse data



Significant reputation / perception issues



Heavily regulated industries



Significant priority and investment in safety



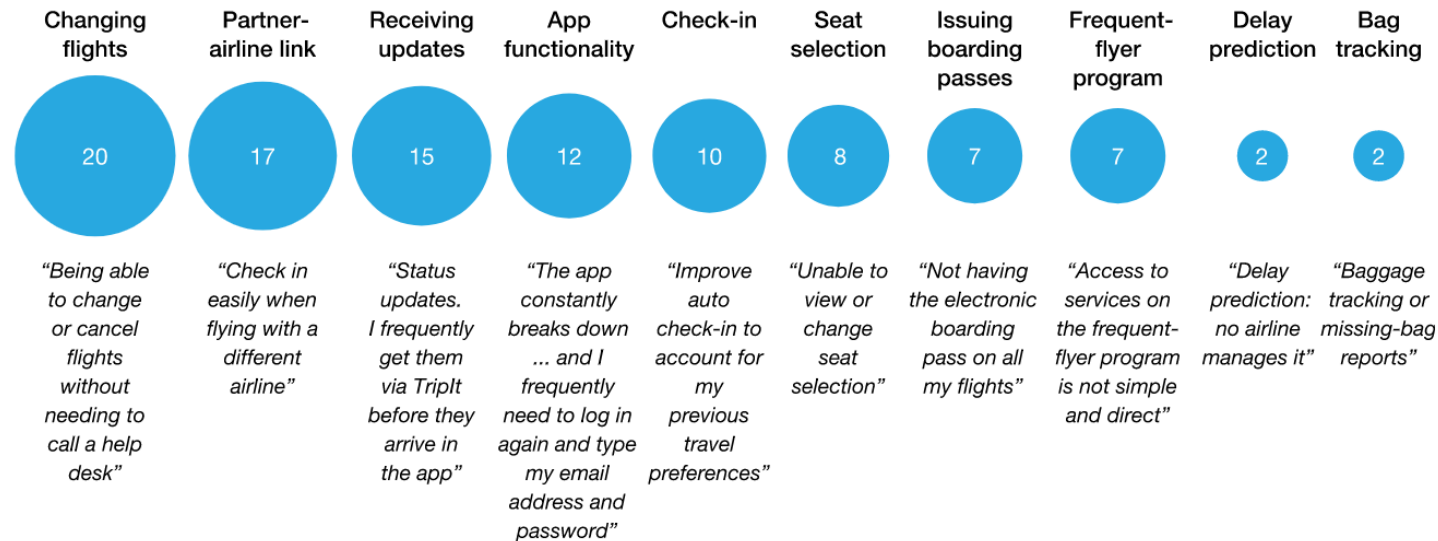
Critical role of supply chain



Increased focus on user experience

Start by Understanding the “User”

Question: Which missing service you expect and consider basic is causing the highest amount of frustration for you as a traveler? % share



McKinsey&Company | Source: Short internal survey of frequent flyers (n = 63), 76% percent of whom take more than 40 flights a year

Start by Understanding the “User”

Patient Group Engagement Across the Clinical Trial Continuum*

Patient groups have potential to enhance the quality and efficiency of clinical trials by providing:

- Financial support for research
- Natural history data
- Input on relevance of research to patients
- Access to translational tools
- Help defining eligibility criteria
- Input on meaningful endpoints & PROs
- Advocacy for policy & funding issues†
- Education to patient community†

- Support to sponsors around key regulatory meetings
- Support preparing submissions for newborn screening for rare diseases
- Informing regulators on benefit-risk†
- Public testimony at regulatory meetings†

Discovery & Pre-Clinical‡

Phase 1 - 3

Regulatory Review

Post-Approval

- Benefit-risk & patient-preference studies
- Protocol design & study feasibility input
- Study recruitment & retention strategy input
- Increased awareness about trials
- Participant feedback on trial experience
- Input on informed consent content & processes
- Peer advocates for participants†
- Clinical trial networks†
- Data Safety Monitoring Board members†

- Phase 1-3 activities and...
- Support interpreting & disseminating study results
- Collaboration on post-marketing studies & surveillance initiatives
- Support developing access strategy & preparing for value or health technology review

*Updated 2018; adapted from Parkinson's Foundation materials | †Patient group activities typically undertaken independently or with partners other than sponsors | ‡Includes early planning for trials

THEMES FOR DIGITAL IN DEVELOPMENT



ACCESS

access to participation
travel, virtual/remote, location-flexible

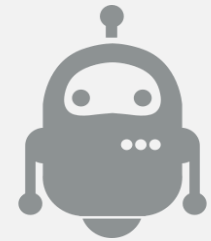
access to information
*pre-trial, during-trial, post-trial
sharing results & data*



MEASURE

improve existing measurement

enable new endpoints



AUTOMATE

process automation

remove tasks

improve quality

Will Digital Tools in Medicine Development enable...

Improvement,

Disruption, or

Displacement?

INCREMENTAL DIGITAL IMPROVEMENTS

study planning



patient engagement



study conduct



analysis & reporting

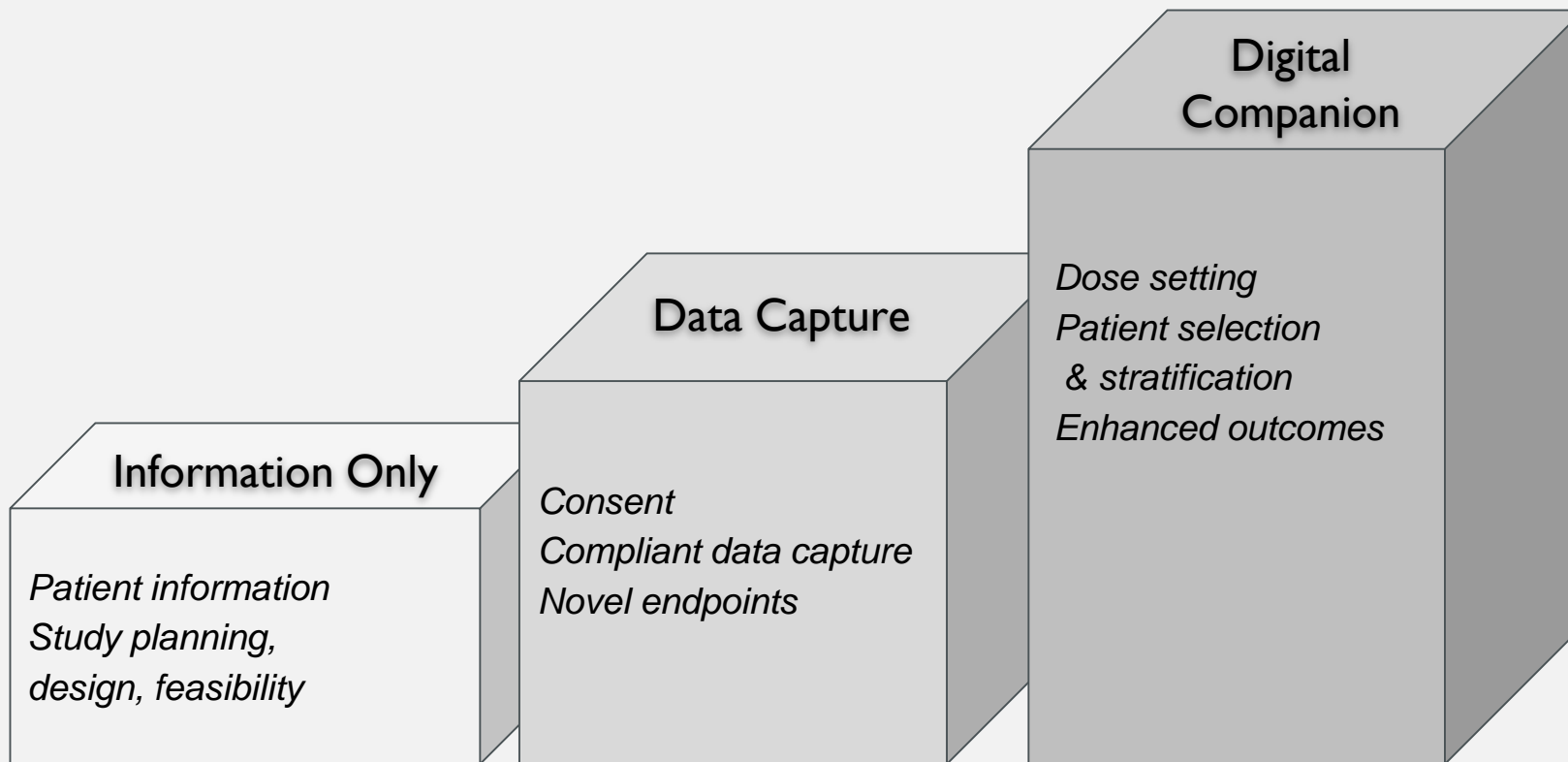
crowdsourcing
data-driven
AI-informed
protocol-fueled
automation

data-driven matching
electronic consent
location-flexibility
digital concierge support
self-tracked & self-reported data
patient aggregated data
sharing results & data
data ownership

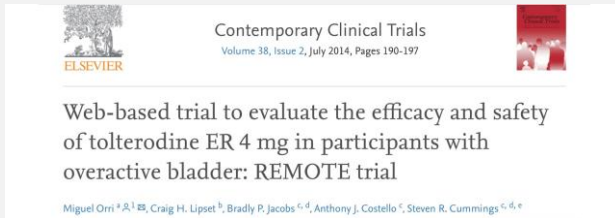
remote monitoring
digital/AI biomarkers
electronically sourced data
RWD/RWE
synthetic controls
process automation

reporting automation
deliverables to participants

DIGITAL AS A DISRUPTOR



Example: DIGITAL DISRUPTING LOCATION



M. Orri et al. / Contemporary Clinical Trials 38 (2014) 190–197

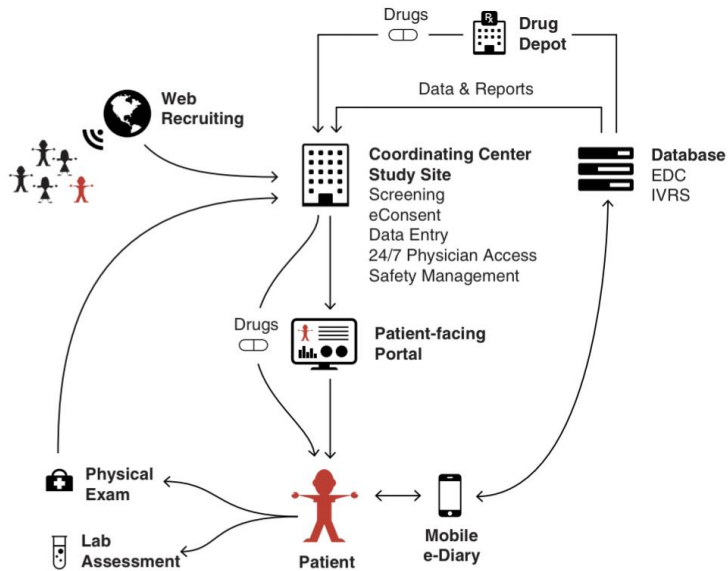
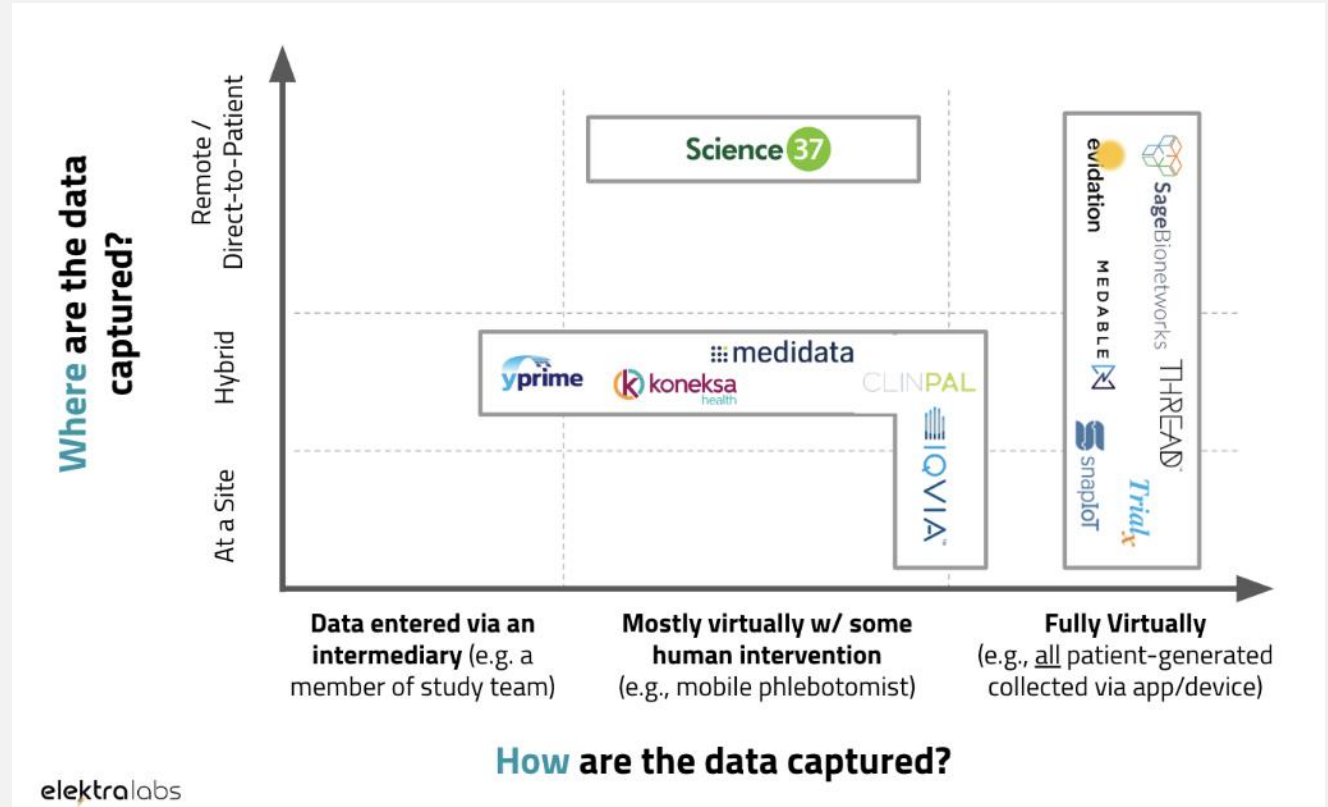


Fig. 2. Electronic data collection and management. EDC = electronic data capture, IVRS = interactive voice response system.



elektralabs

Andy Coravos, CEO Elektra Labs @ElektraLabs

DIGITAL ENABLING DISPLACEMENT



**DIY
R&D**



Patient-Led



**Digital
Twins**

What stands in the way
of realizing the impact
of digital in medicine development?

WHAT IS MISSING?



Easy



Scale

WHAT IS MISSING?



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