



Digital in Pharma Development

DCRF subsession – Patient Generated Data
October 4, 2017

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Less than 2 decades ago ...

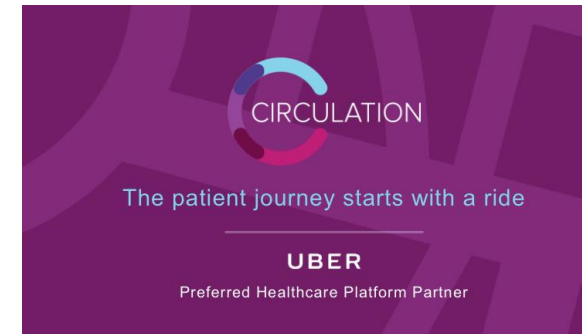


25 years later

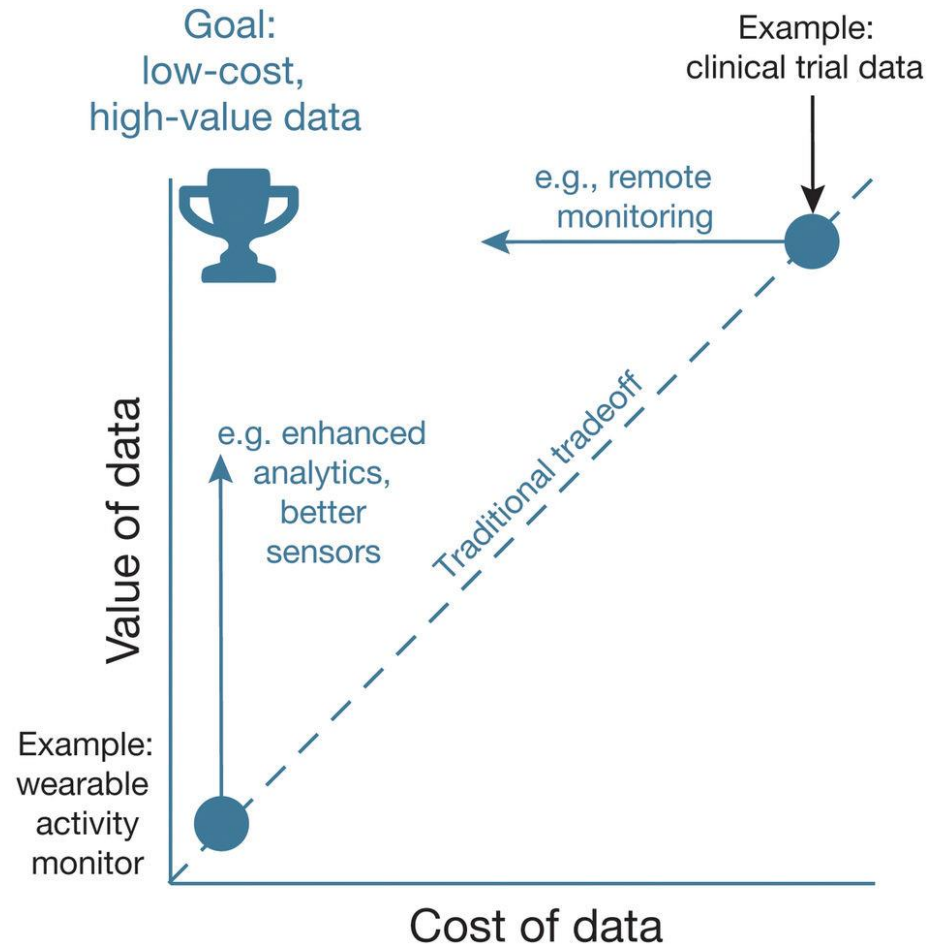


A disruptive example: Artificial Intelligence in Clinical Trials

- Likelihood to get a certain disease
- Clinical trial site's feasibility
- Smart knowledge management / decision support
- Identify categories of eligible patients



The Holy Grail



Source:
Nature Biotechnology 33, 910–920 (2015)

Adoption of Digital by Pharma in clinical trials



65%



97%



70%



Source:
Validic - Insights on Digital Health Technology Survey 2016



WHY Digital in Clinical Trials

73% Demonstrate efficacy and real-world value

68% Reduce trial costs

68% Patient-centricity

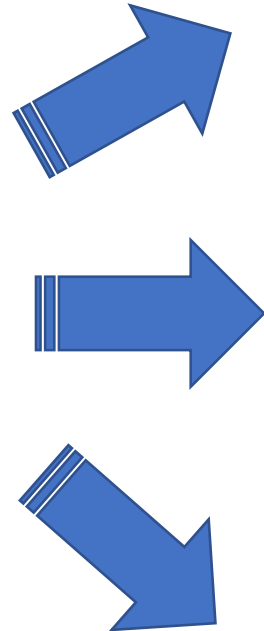
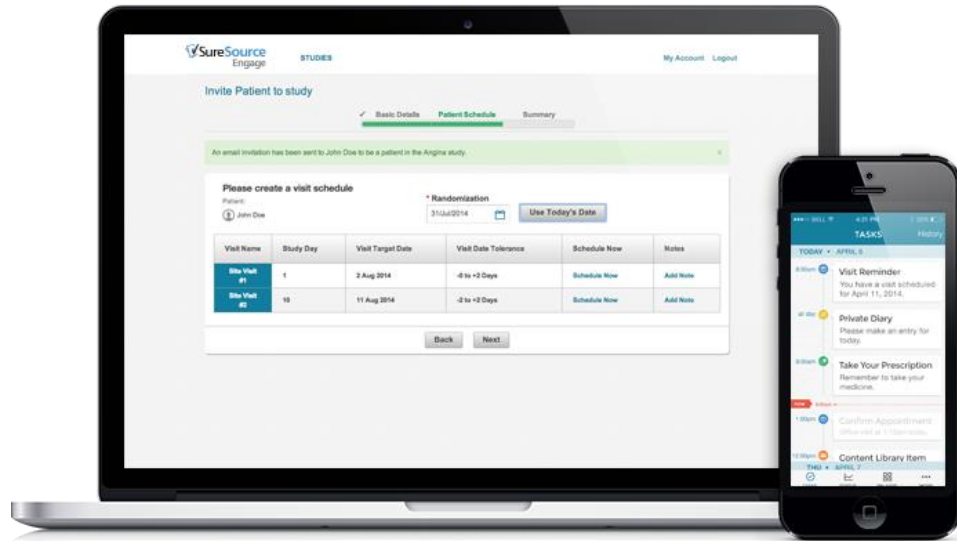
59% Streamline trial processes

46% Precision medicine

35% Competitive differentiator

Source:
Validic - Insights on Digital Health Technology Survey 2016

The future of clinical trials



Patient Journey App

<https://patientjourneyapp.nl/>



<http://www.scriptdrop.co/>



<https://vimeo.com/138783051>

Biggest challenges for pharma in virtual trials



TRUST



INNOVATION



PATIENTS
INCLUDED

And also:

What are the **key concerns** you have when it comes to using digital health data? (Rank order, 1 being the top concern.)



1
Accuracy of data



4
Knowing what device to use



9
21 CFR Part 11 compliance



10
I'm afraid digital health data will demonstrate negative results for the drug or therapy



2
Standardization of data



5
Integrating data from devices into your clinical trial platform or system



7
Physicians' ability and willingness to use digital health devices



11
I'm afraid the FDA will reject trials results that include digital health data



3
How to analyze the data in a meaningful way



6
Patients' ability and willingness to use digital health devices



8
Lack of guidance from the FDA on devices



Let's start the discussion: are patients sufficiently included?