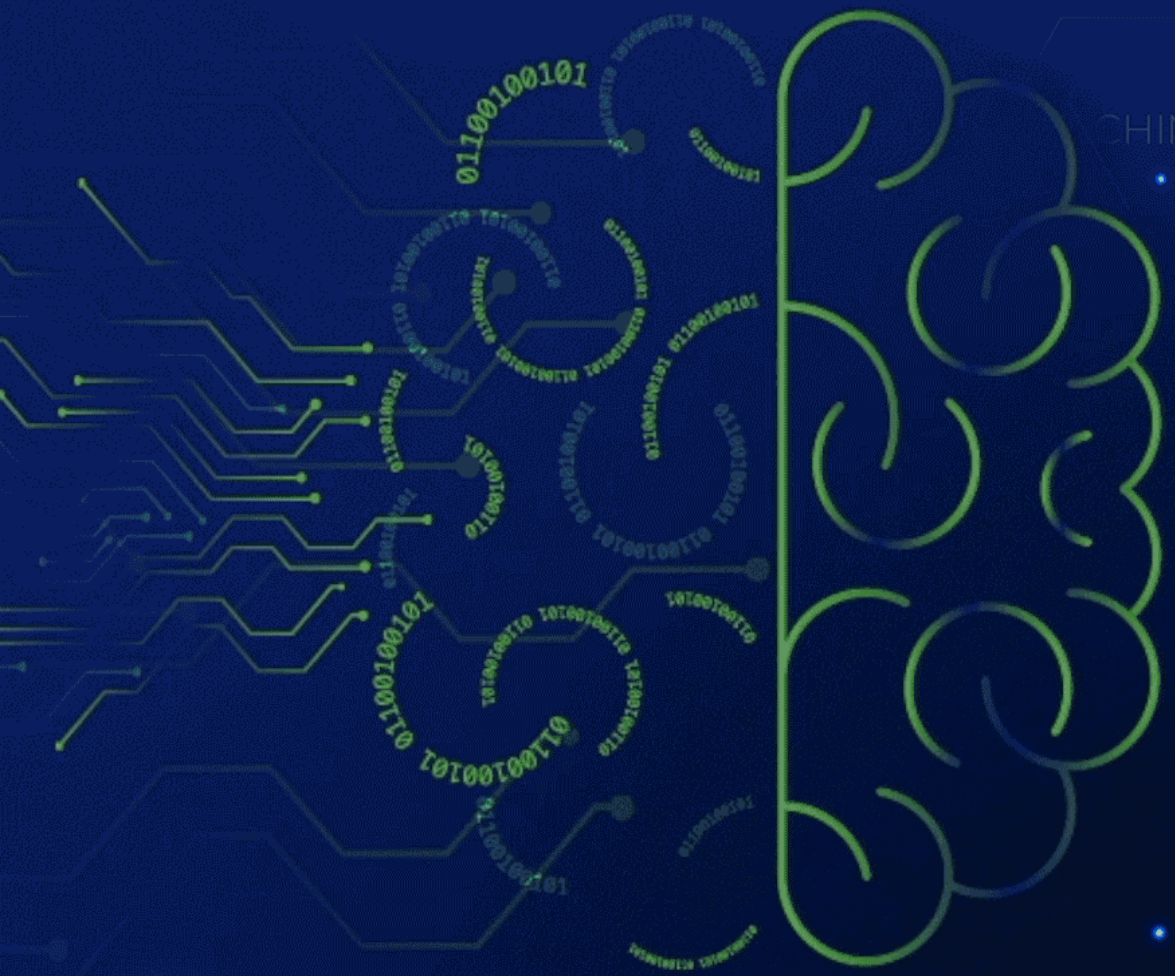

MORE THAN BUZZ- REAL-WORLD EXAMPLES OF LARGE SCALE DCT

MEGAN PETRYLAK

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MORE THAN BUZZ-REAL-WORLD EXAMPLES OF LARGE SCALE DCT

Rashida Rampurawala - CCDM®, Manager – Clinical Data Management, GSK

Megan Petrylak – EVP, Customer Delivery, Clinical ink

SCDM 2022
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San Antonio, Texas
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Objectives

- Present real-world case studies where implementation of DCT solutions solved for trial challenges
- Demonstrate the implementation of DCT solutions provide a more patient-centric experience
- Provide data showing that DCT solutions are a tried-and- true practice for support of clinical trials
- Engage in a collaborative discussion on lessons learned as DCT has evolved over the past decade

STATISTICS SUPPORTING GREATER DCT ADOPTION

70% of participants live greater than 2 hours from an investigator site

Patient access to trial sites was reduced by 80% with the onset of COVID-19

•70% of respondents have been involved in or worked on trials that have implemented some decentralized element in the last two years.

•58% say decentralized trials are faster than traditional trials in their experience, saving respondents on average just under 3 months to completion.

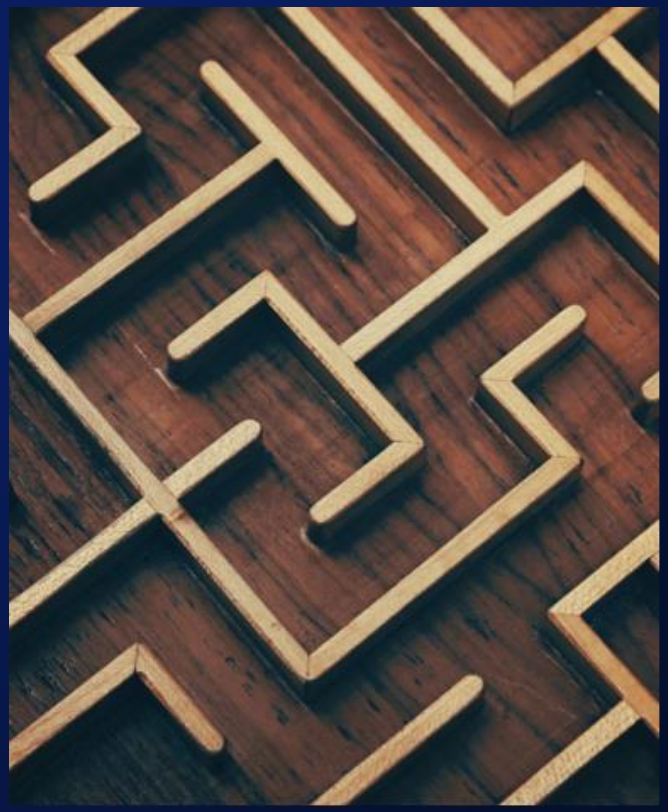
•71% say decentralized trials are better for patient recruitment than traditional trials, and 74% for retention.

•81% say decentralized trials cost about the same or have a lower overall cost than traditional trials

•50% of clinical trials will be either hybrid or virtual by 2024

•73% of survey respondents believe the costs of decentralized trials are worth the benefits

•40% of respondents of a survey say their companies have participated in DCT pilot or proof of concept studies



Takeaway: DCT can help solve challenges faced to date in running successful clinical trials

https://informaconnect.com/report-impacts-decentralized-clinical-trials-2021

https://www.mckinsey.com/industries/life-sciences/our-insights/no-place-like-home-stepping-up-the-decentralization-of-clinical-trials

LESSONS LEARNED OVER LAST DECADE

Participants want a choice- many are juggling coping with serious health issues, full-time jobs, raising families and challenging economic times

•Finding potential participants has been challenging (for example, in rural areas where travel to/from sites is difficult). More patients would be able and willing to take part if participation is easier, reducing the recruitment burden on CROs and sponsors.

•Participant diversity is essential- need to draw from a wider pool rather than limit recruitment to participants within a reasonable distance of a participating site.

Participants are more knowledgeable, informed and engaged as a result of access to technology

Incorporation of remote monitoring allows for real-time access to trials data which enables less bias and better PI oversight.

•The accuracy and reliability of data has improved by the reduction in paper source data that can be lost or damaged, forms inaccurately filled out or transcription error

Takeaway: DCT solutions offer a more patient-centric approach while also improving the quality of data for clinical trials

Advantages of DCT

- **Choice -** Patients who might ordinarily be reluctant to participate in a clinical trial may now be able to do so without having to worry too much about the logistics.

- **Convenience -** Data can be accessible during a "virtual" trial at any time, anywhere, with support available around the clock.

- **Collaboration -** All parties can work together very instantly when using digital tools, which cuts down on pointless back-and-forth communication.

- **Cost -** Faster enrolment allows for quicker completion of the clinical trial, which saves the sponsors a significant amount of money.

- **Diversity -** They allow participation from many population groups, such as the elderly, the impoverished, those who live in rural areas, or members of minority ethnic groups, who ordinarily might not want to participate in a study.

DCTs are made possible by modern digital data collection techniques and technologies, such as e-Consent, wearable medical equipment, eCOA/ePRO, online surveys, telehealth visits, medication home delivery, nearby lab testing, and remote monitoring. These techniques also assist in resolving many problems that prevent patients from enrolling in and completing trials.

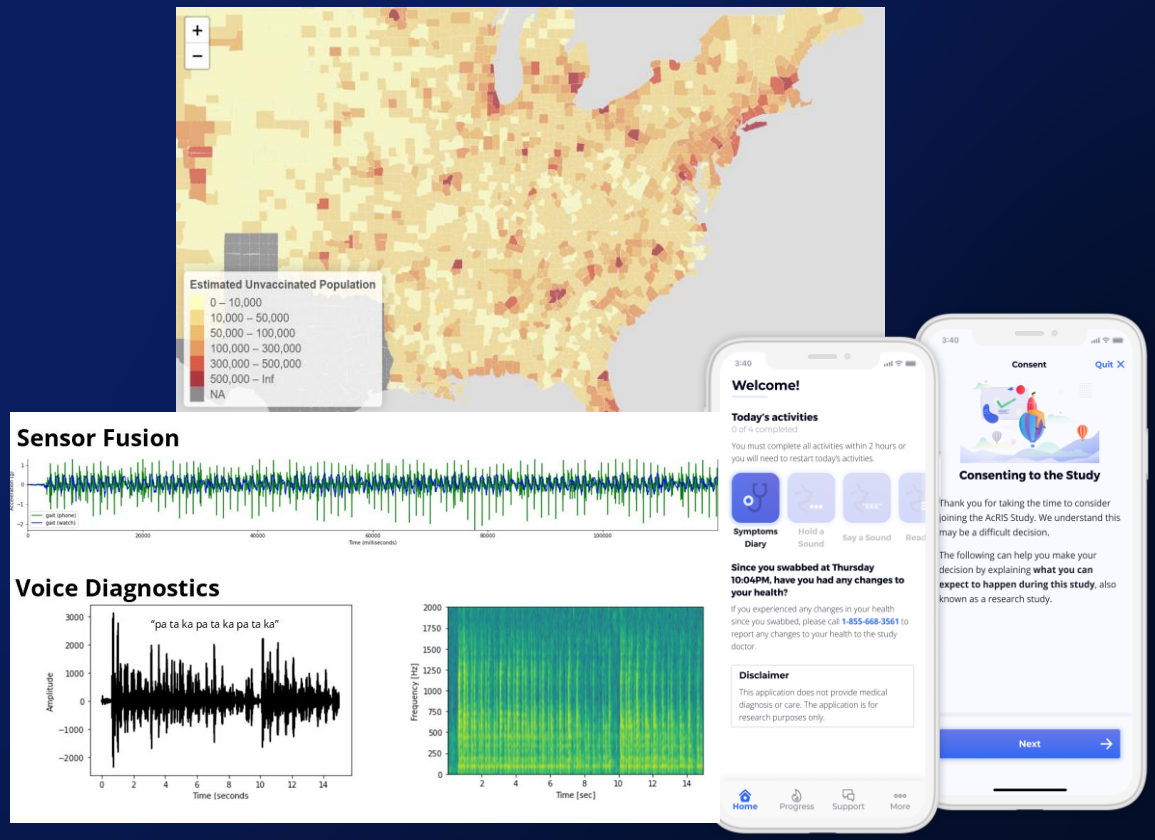
CASE STUDY: DCT by Design

Study Specs	
Phase	III
Indication	Early Onset Alzheimer's Disease
Patients	6,000+ patients/caregivers enrolled
Issue	Screening of more than 20,000 potential patients in an older Population with caregivers and the need to perform assessments remotely
Approach	Patients and caregivers using provisioned devices to carry out assessments remotely. Patients will be able to draw images (clock, 3D box and the trail making test) from home Assessments, all done remotely, including CDR, Category Fluency, MoCA, C-SSRS, and other cognitive assessment. 50+ Remote Assessors, 5 year duration; Continuous follow up

Takeaway: Complex Indications can be done remote with careful study design planning!

CASE STUDY: Fully Remote, Novel Endpoints

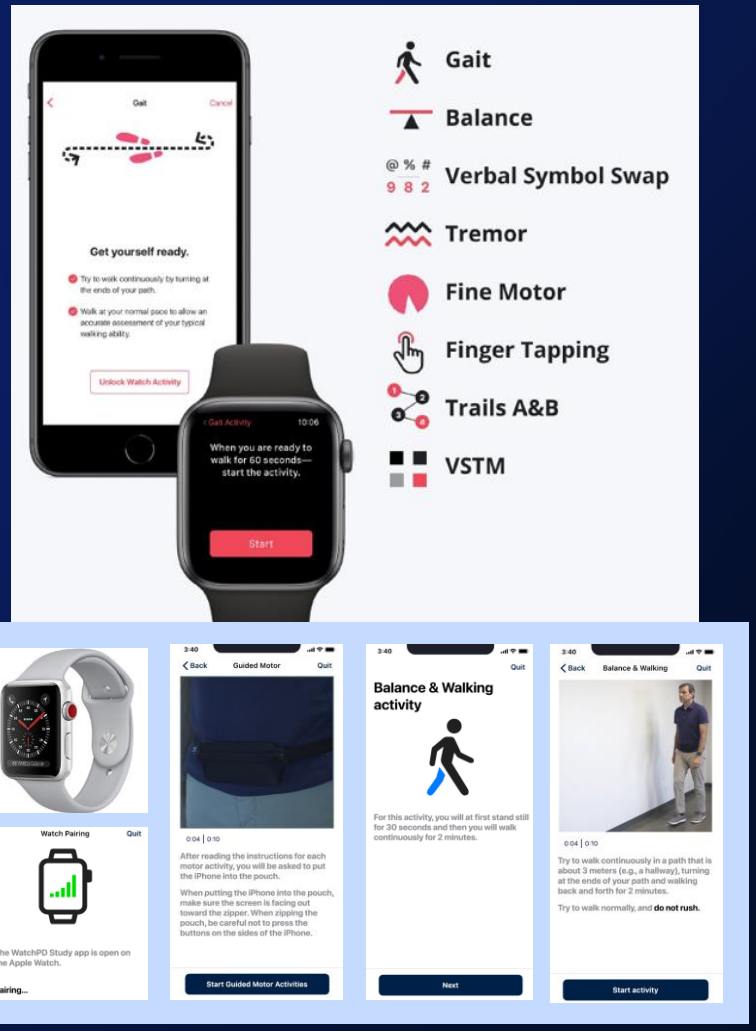
Study Specs	
Indication	Acute Respiratory Illness
Patients	10,000+ patients
Issue	Can completely ‘at-home’ enrollment and participation yield novel insights regarding symptoms measured by voice assessments? Can differences in disease be detected based on audio recordings?
Approach	The entire patient experience conducted on BYOD. Recruitment, Consent, Data Capture, Payments – all in a single platform – 100% remote
Results	Custom patient facing platform developed in less than 3 months with CDC Surveillance reporting. 95% of participants who completed surveys continued to complete voice tasks, suggesting voice tasks were not a burdensome point of the study protocol.



Takeaway: 100% remote is possible! Symptoms can be measure by voice assessments! Use Novel endpoints to change traditional clinical trial assessments

CASE STUDY: Convergence of eCOA and Sensors

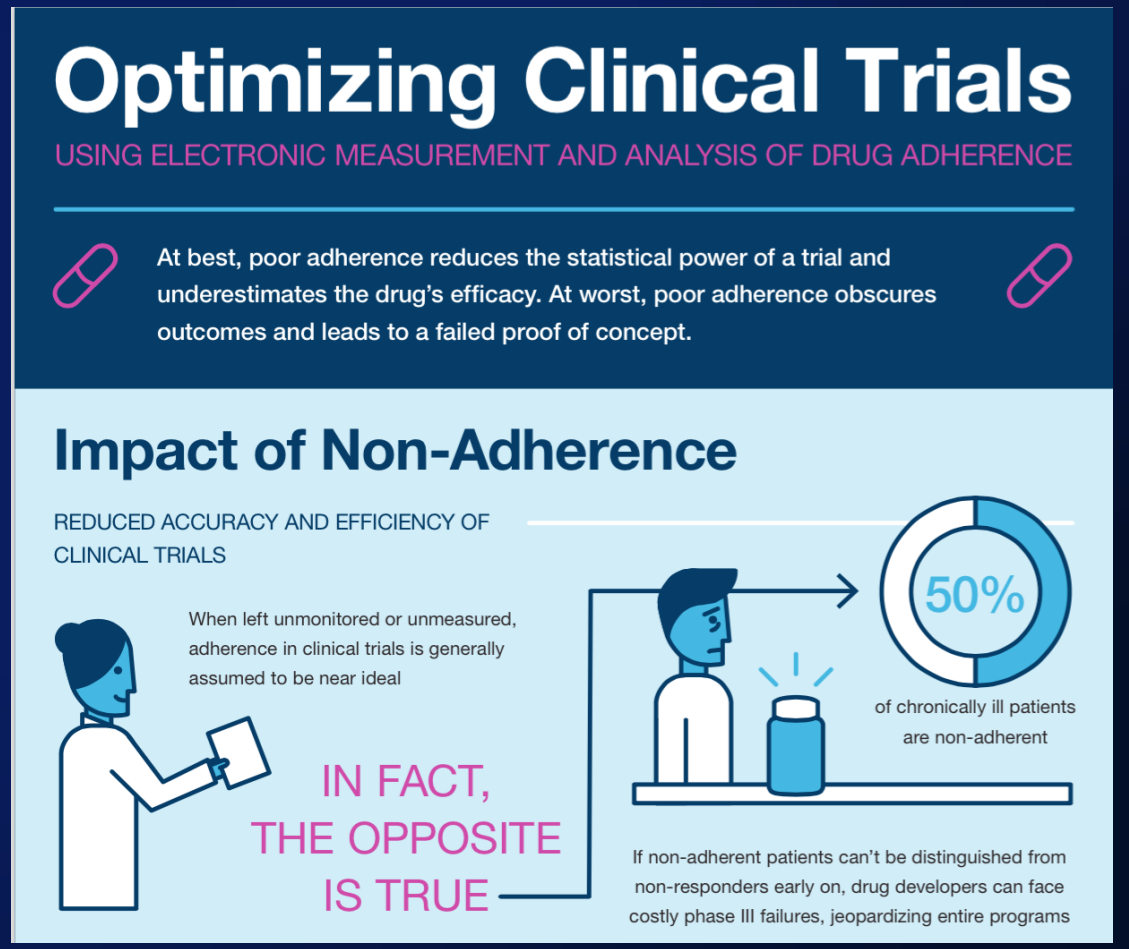
Study Specs	
Indication	Parkinsons
Patients	132 patients
Approach	Can ‘at-home’ measurement provide greater insights into disease progression than clinic visits alone? 6 Clinic visits – 1, 3, 6, 9, 12 months 2x Monthly assessments; continuous passive data 7 days post-visit (watch & phone)
Goal	Can a customized wearable/mobile platform used outside of the clinic meaningfully supplement in-clinic measures of PD motor and non-motor symptom progression?



Takeaway: Meaningful data from sensor-derived and mobile measures by linking to patient-reported QoL and ADLs (e.g., UPDRS 1/2, PDQ-8, SCOPA, GDS)

CASE STUDY: ADAPTABLE - Aspirin Dosing: A Patient-centric Trial Assessing Benefits and Long-term Effectiveness

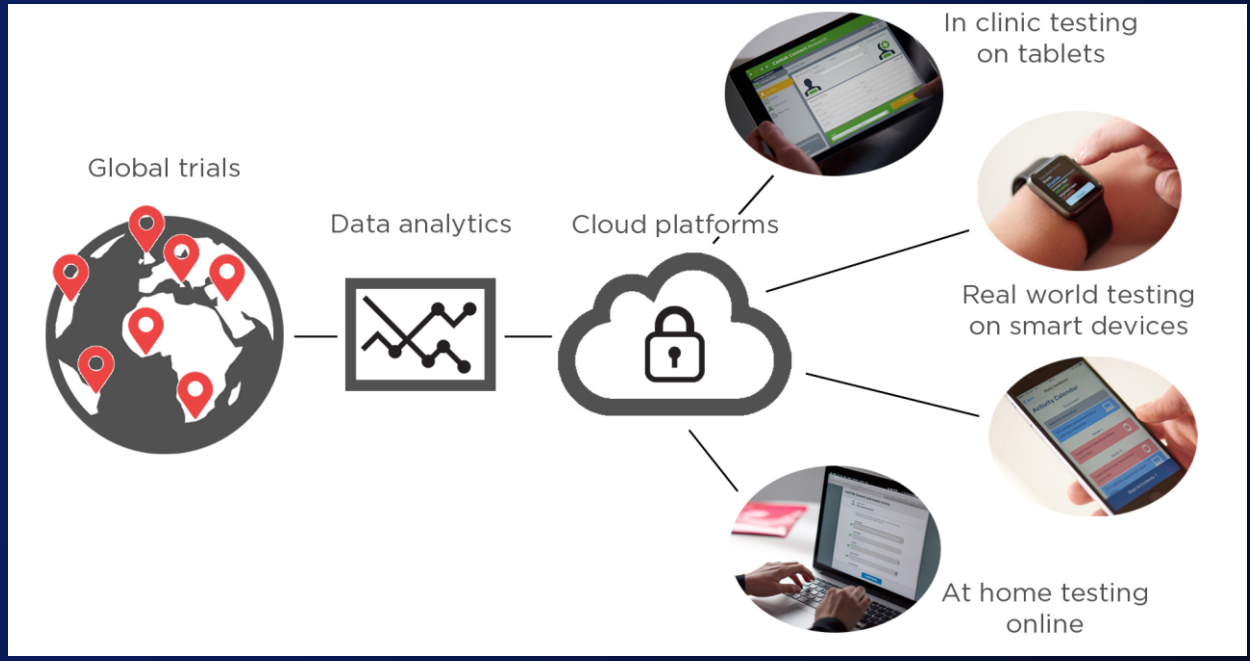
Study Specs	
Phase	III
Indication	Cardiovascular Trial
Patients	15,076 patients across 40 centers
Study Details	The goal of the trial was to evaluate aspirin 81 mg compared with 325 mg among patients with established atherosclerotic cardiovascular disease (ASCVD). Recruitment was the biggest challenge as not many people were willing to participate.
Approach	ADAPTABLE study team had assembled a variety of platforms and collaborators. An easy-to-use web application that acts as the patient-facing interface for 100% virtual trials and hybrid studies was used. Robust technology was used to remotely manage the ***enrollment, randomization, and informed consent*** processes. Participants were also able to simply report their health results during the trial from the comfort of their homes.



Takeaway: high rates of visit completion, adherence, and retention

CASE STUDY: Research on Electronic Monitoring of OAB Treatment Experience (REMOTE)

Study Specs	
Phase	IV
Indication	Gastrointestinal Trial
Patients	600 patients from about 10 states across the United States.
Study Details	To compare the effect of tolterodine ER 4 mg to placebo on patient reported outcomes in subjects with overactive bladder after 1, 4, and 12 weeks of treatment using an innovative web-based trial design
Approach	Enrolled patients will actively manage their own trial activities, take part in the study screening process online, and report results to a trial investigator who closely monitors patient eligibility and safety. As a result, by increasing patient compliance, reducing withdrawal rates, and collecting data in real-time, researchers anticipate saving time and obtaining better quality, more trustworthy data.



Takeaway: Virtual Clinical Trial Allowing Patients to Participate Regardless Of Geography.
Decreasing the burden and training curve of using DCT methodologies can broaden the reach of those trials and progress the industry towards broader flexibility in trial conduct

Points to Consider

Plan early and be ready to pivot

Map and understand your data flow

Know your patient population

Remember: it's all about the patient

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Demystifying Decentralized Trials - Best Practices, Pitfalls and What DataManagers Need to Know