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Single Day Event

Virtual Trials :The Cat's Out of the Bag

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Amelioration of Virtual Trials

Agile Clinical Trial Model

Agile Clinical trial - a multi-modal approach to research encompassing **decentralized, on-site, or the full spectrum of hybrid clinical trials**—delivering flexibility to add traditional and non-traditional elements into the mix as an extension to trial design.

The Industry is Moving Towards Agile

77%

of sponsors will be running an Agile (hybrid) Clinical Trial in 2022

Improve Enrollment and Retention

Scale recruitment, connect any patient with any provider, and conduct visits anywhere.

Site independent procedures

With centralized networks, procedures don't need to be conducted primarily at sites.

Execute Faster Trials

Meet deadlines efficiently without sacrificing quality.

Incorporate Existing Sites

Enhance flexibility for the patient and give access to high-performing sites and KOLs.

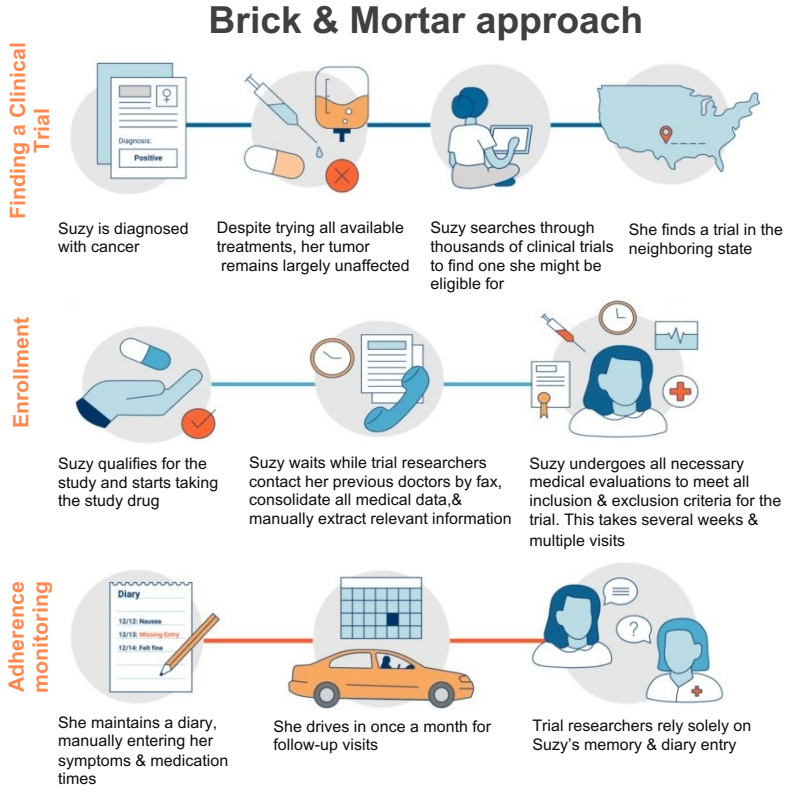
Enable Greater Diversity

Generate a more real-world representation with robust recruitment and expansive network

Enhance Compliance

Enable greater compliance with unified technology that delivers an intuitive experience.

AI – The “Game Changer”



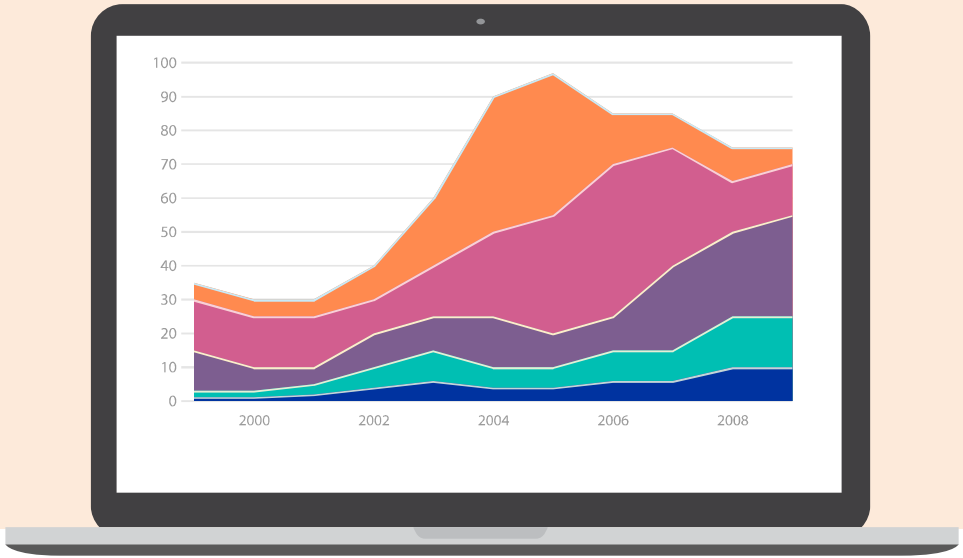
Artificial intelligence - powered technology has the potential to change every stage of the clinical trials process, from finding a trial to enrollment to medication adherence.

Finding a clinical trial using NLP

Enrolment enhancement using Telehealth services

Medication adherence using Visual, Auditory & Digital Phenotyping

Matching a clinical trial



- Natural language processing (NLP) can help extract and analyze relevant information from a patient's EHR records, compare with eligibility criteria for ongoing trials, and recommend matching studies.
- Deep 6 AI is one such company which accelerates patient recruitment exponentially, getting life-saving treatment to patients more quickly.
- Deep 6 AI uses NLP to extract clinical data such as symptoms, diagnoses, and treatments from patient records. Its software can even identify patients with conditions not explicitly mentioned in EHR data, improving the match rate between patients and clinical trials

Other emerging consumer-focused recruitment solutions include:

- Disease-specific social networking platforms like Be the Partner
- Open-source frameworks like Google Health Studies, which researchers can use to create their own apps for conducting research studies

Inclusion Criteria- Procedures

Breakthrough's

Telehealth Services could help streamline this process

Tyto's device and accompanying smartphone app allows patients to carry out their own exams

Share results in real time with remote physicians by capturing data from the heart, lungs, throat, ears, skin, and abdomen

Inclusion Criteria:

- Participants must have histologically or cytologically confirmed invasive breast cancer, with metastatic disease. Participants without pathologic or cytologic confirmation of metastatic disease should have unequivocal evidence of metastasis from physical examination or radiologic evaluation.
- Prior chemotherapy: Participants may have received 0-3 prior chemotherapeutic regimens for metastatic breast cancer and must have been off treatment with chemotherapy for at least 14 days prior to registration. Participants should also be adequately recovered from acute toxicities of prior treatment.

Challenges

Preliminary phone screen

Examination by a participating site in person or virtually (can involve lab tests and imaging results)

Accessibility of the patients to the collection centers

Medication Adherence

Prone to human error

- In traditional trials Drug regime tracking is dependent on patient diaries
- Many clinical studies still use paper diaries instead of electronic systems.

Process plagued with Inefficiencies

- Reliance on patient memory
- Outdated recording system
- Risk of drop out.

Non-Adherence leading to AE

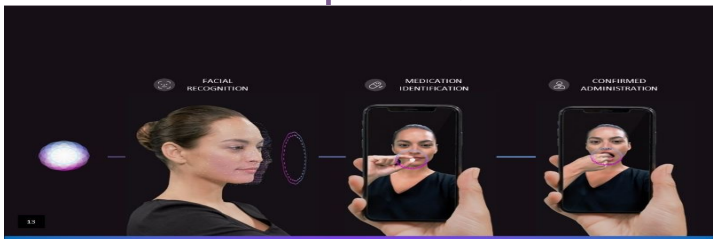
- Generally, adherence rates of 80% or more are required for therapeutic efficacy.

AI Platforms - AiCure

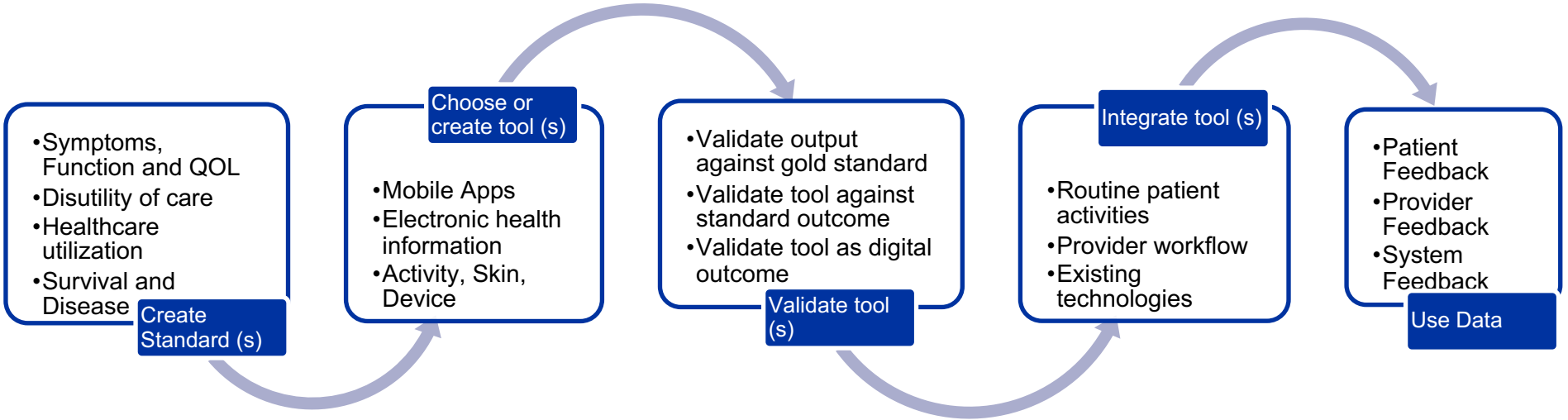
- Use an interactive medical assistant (IMA) to identify patients at risk of non-adherence based on visual data collection

Digital Phenotyping

- Patients use their phones to take a video of themselves swallowing a pill, and AiCure confirms that the right person took the right pill



Digital Devices Development Life Cycle (DDLC)

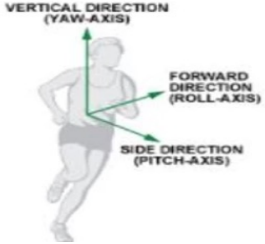


Digital Outcome Measure - Challenges

- Adoption of condition specific outcomes
- Capturing, validation and translation of outcomes
- Integration of new data streams to current workflow
- Cost effectiveness

Data Quality – Technology and Accuracy

Algorithm of Pedometer

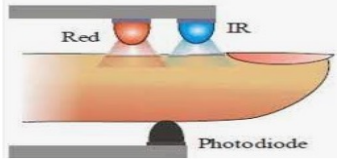


- **Step 1** – Start calibration
- **Step 2** - Continuously gets the data from X, Y, and Z-axis
- **Step 3** – Max and Min values of all Axis
- **Step 4** – Compare Max and Min with Threshold values
- **Step 5** – Acceleration > Threshold value then increase

Why Green Light?

- Spectroscopy – Color Reflection and Absorption
- Photo plethysmography – Heart Rate
- Less susceptible to ambient light
- Pulse rate calculation and challenges
- Oxygen saturation (SpO2) calculation

Pulse Oximeter



- Oxygen saturation – SpO2
- COVID 19 - Hypoxia
- Two light sources – Red light and Infra Red light

Real time Applications

The effect of Walking Program With Pedometer on Quality of Life in COPD – Chang Gung University

Study been conducted to measure:-

> PFT, 6 Min Walking Test (6MWT), COPD assessment test, QOL questionnaire (SF-12)

Using Smart Watches to Detect and Monitor COVID-19 (CovIdentify) – Duke University

> Validate and test the specificity and sensitivity of the models detecting COVID-19 infection Vs. non-infection against symptom surveys and COVID-19 test results

Home pulse oximeter Use in Patients with COVID-19 – Swedish Hospital

> Investigate the use of home pulse oximetry monitoring in patients with COVID-19 to trend disease progression and identify need for hospitalization

Smart Textiles

Examples

Nadi X yoga pants – Wearable X

Accelerometer and Haptic motor - guiding Yoga steps

Women's leggings - Athos

Scan Biosignals – Muscle Activity, Heart rate and Calories burnt.

Smart Shirts - Hexoskin

Textile sensors – Cardiac, respiratory, activity, stress, cognitive and sleep research

Smart Socks - Sensoria

Assist runners – Identifies injury prone running techniques. Detects cadence, foot landing etc…

Real Time Applications

Smart Textile Technology for Scoliosis –

University of Minnesota

> To hypothesize that a garment integrated sensing system will be able to detect with clinical accuracy the position of the spine.

Posturographic assessment by means of Novel E-Textile and wireless socks device –

University of Naples

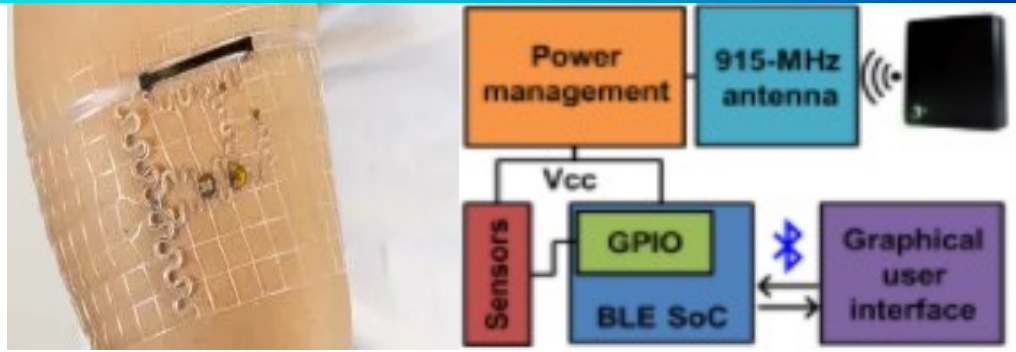
> Twenty Posturographic tests has been performed on normal subjects at the same time both by pressure signals derived by Sensoria fitness (SF) e-textile socks and by a gold standard stabilometric Zebris platform (ZP).

Hexoskin feasibility study with COVID-19 patients –

Nguyen Thu Ngan Trinh

> To generate quantifiable information regarding the feasibility of a virtual trial with the Hexoskin platform, collection of physiological data quality in COVID-19 patients and values for algorithm construction.

Compact Wearable – Lab on the skin Biosymbiotic Device

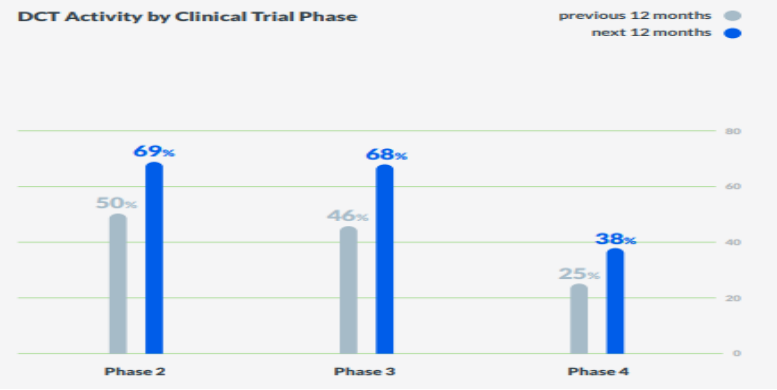


- Wearable from Laboratory for Nanobioelectronics / University of California San Diego
- Continuously monitors Glucose (Spikes/Dips) with Alcohol and Lactate levels in real time
- Velcro-like patch of disposable microneedles, worn on upper arm. Data shared through App.
- Reusable battery and sensors

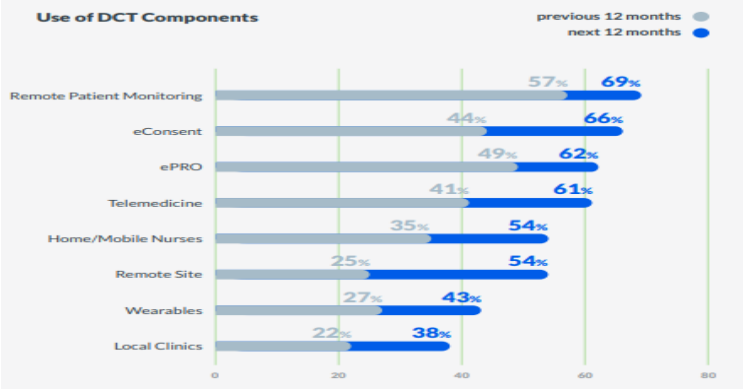
- 3D print medical – grade wearables – by University of Arizona
- Monitoring in Treatment of devices, testing of new drugs and track personal health
- Wireless power transfer and compact energy storage
- unnoticeable, lightweight, breathable, mesh cuff designed
- Non adhesive and water resistant

Decentralized Clinical Trials Adoption – Responders data

Clinical Trial Phase



DCT Components



Biggest Benefits

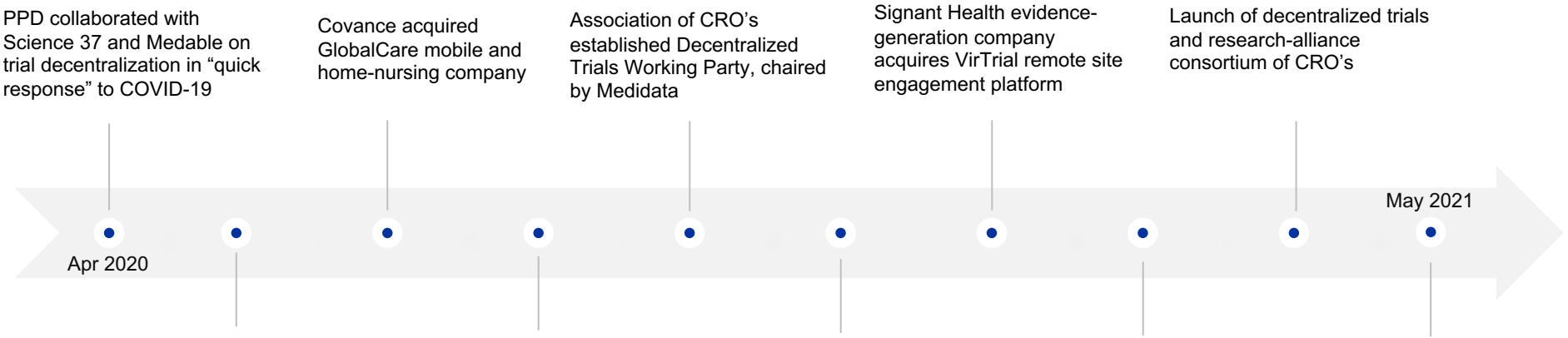
- Better Patient Experience
- Better Patient Retention
- Faster Recruitment
- Lower Costs
- Faster Setup

Biggest Challenges

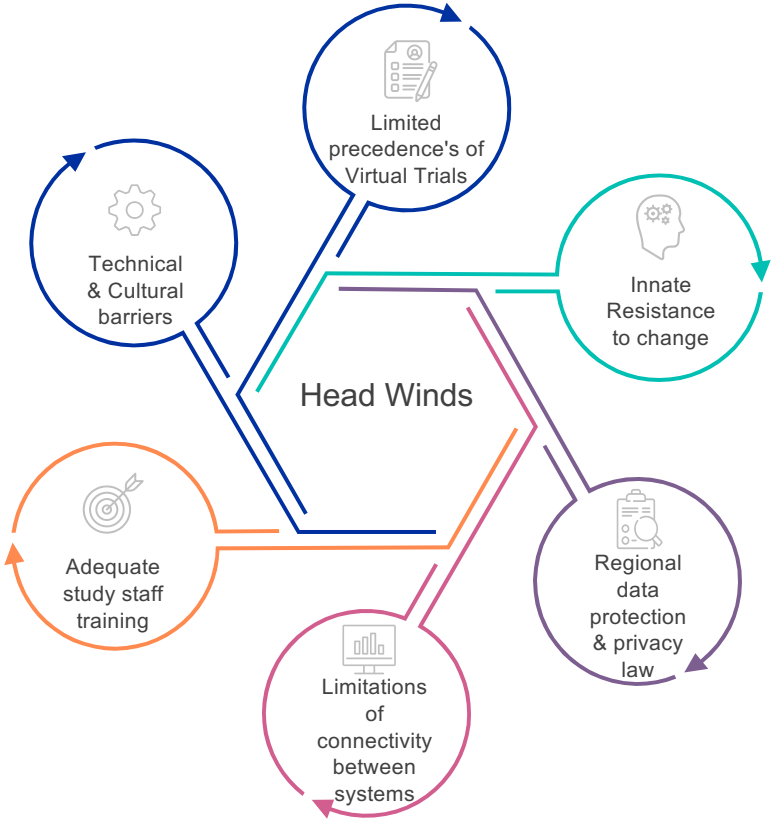
- Integrate Sites + DCT
- In house capabilities
- Regulatory Concern
- Data Privacy / Security
- Lack of Training

Industry adaptation-Virtual Trials

Clinical-trial-ecosystem expansion at scale over 12 months



Future & Path Ahead



- The COVID-19 pandemic has exposed the importance of decentralization in making clinical trials more patient-centric.
- The hallmarks of successful decentralization are likely to remain:

✓ Leadership articulating strategic intent about the opportunities for patients, physicians, and sponsors Strengthening decentralization capabilities across the organization

✓ Embedding reframed processes and systems to support the agenda

✓ Showcasing and celebrating successful decentralized trials across the organization.

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