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Single Day Event

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Pragmatic Clinical Trials in Virtual Environment

Pragmatic Clinical Trial

Pragmatic clinical trials (PCTs) are designed to investigate and evaluate the effectiveness of interventions in real-life practice conditions.

PCTs use the data collected in electronic health record as a part of routine care or embedded in routine care.

Main components of PCTs are;

- Large sample size
- Diverse Settings
- Simple Design
- High External Validity
- Mostly Phase IV

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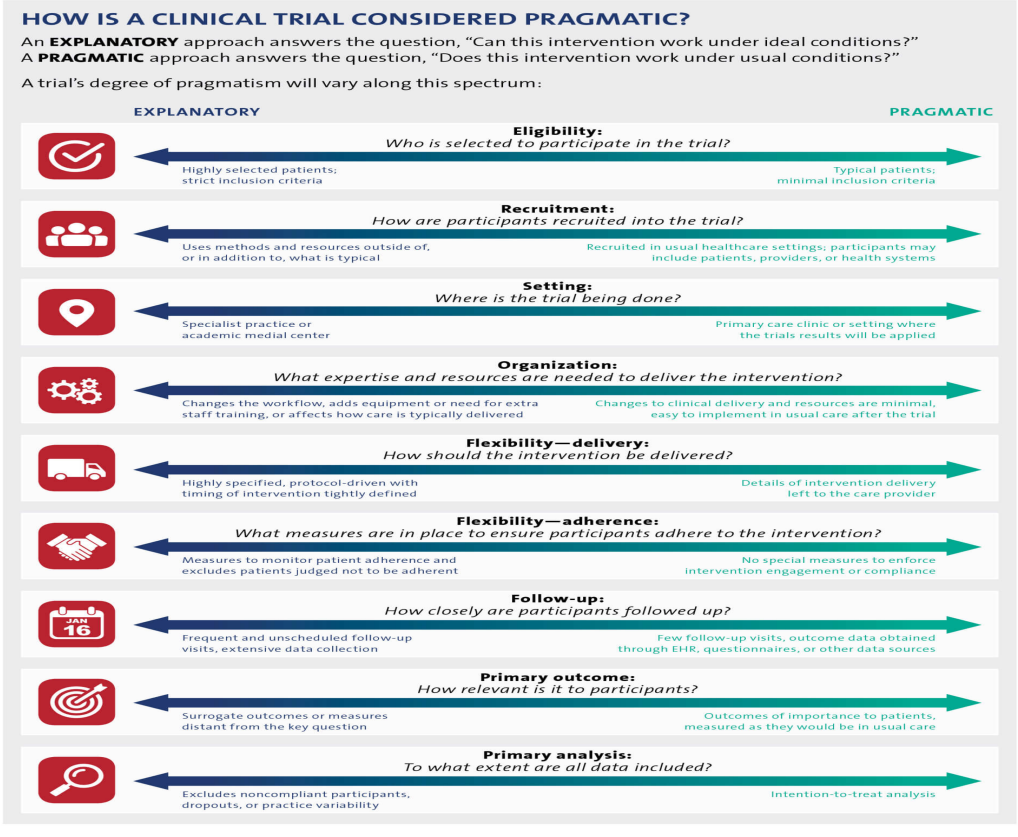
Pragmatic Clinical Trial	Characteristics	Classic Randomized Clinical Trial
Effectiveness testing	Purpose	Efficacy testing
Broad	Inclusion criteria	Selective
Few	Exclusion criteria	Many
Minimal	Burden	High
Simple, waived in specific situations	Informed consent	Complex
At clinical site (cluster)	Randomization	At participant level
Easy to collect, small number	Outcomes	Might be harder to collect
Long-term with data linkage	Follow-up	Short-term
Few, simple, patient-centered	Study procedures	Multiple, complex, research centered



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Virtual Environment for Clinical Trials

A huge thanks to advanced technology and rapid innovation in health care technologies, conducting clinical trials virtually albeit in hybrid mode has become a reality.

As in any methodology it has advantages as well disadvantages. Let's see what are those;

Pros:

- Being able to collect data irrespective of external factors. For ex: pandemic, natural disasters etc.
- Subjects aren't required to travel and make frequent visits to an investigative site
- Subjects feel empowered by being able to participate at their convenience
- Subjects spend less time in a medical office

Cons:

- Subjects will not have face to face interactions with study staff
- Facing technical problems

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Clinical trial research companies believe the use of patient-facing technology helps in widening the pool of trial participants/volunteers, extended patient retention, better data quality, and a holistic patient-centric experience.

It is also believed that virtual clinical trial solutions can significantly improve site staff recruitment, patient recruitment campaigns, safety monitoring, patient education, pre-screening, and data verifications.

In terms of key benefits, cost efficiency is significant with virtual clinical trials and is expected to have a positive impact on the bottom-line figures of the pharmaceutical companies.

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Implementation of these decentralized and remote solutions also enables better time-to-market for new drugs by reducing the overall time period of the clinical trial lifecycle. It also derives benefits through reduced enrollment periods, faster study initiations, lowered patient dropouts, and improved data collection features.

In several cases, it is reported that the overall cost of conducting virtual clinical trials is lower than the conventional clinical trial methods due to remote visit set-ups. This in turn offers capital savings due to reduced number of operational clinical sites. Further cost-benefit is extracted from reduced patient travel reimbursements.

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Traditional vs Virtual Clinical Trial Process

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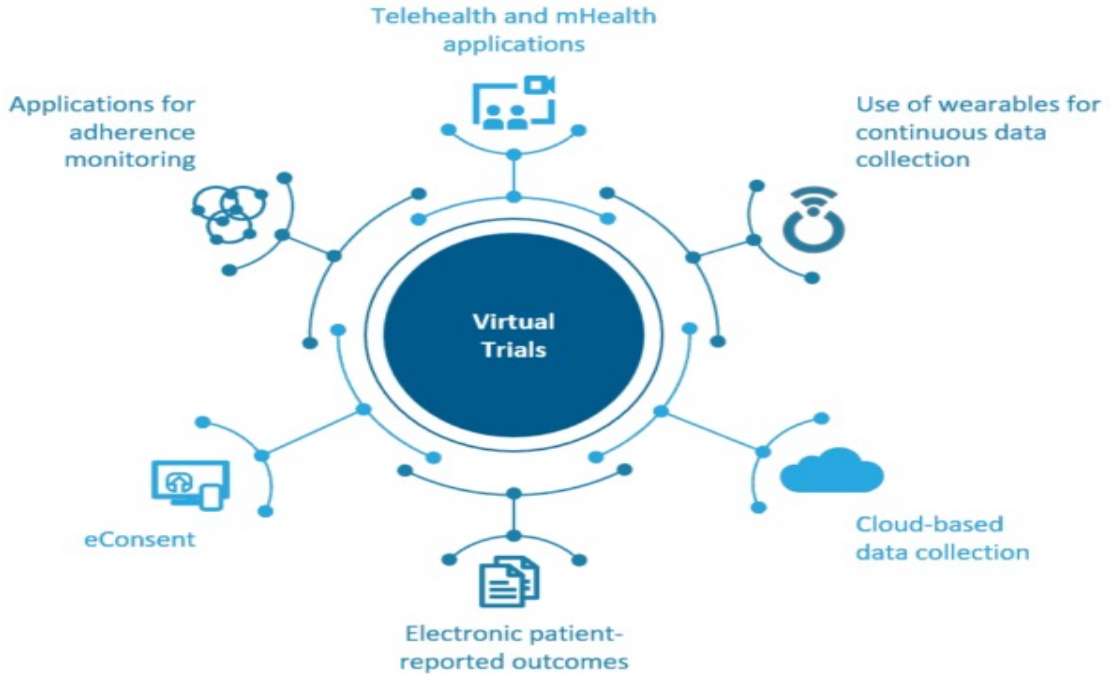
Some components that enable a trial to be virtual



Virtual trial benefits

Cost effective

The number of actual sites participating would decline, which would reduce site setup, monitoring, and associated costs

Increased patient enrollment

Patients with mobility issues can participate

Reduced patient dropouts

Due to less frequent site visits and digital and automated data collection, the dropout rate would decline

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How PCTs in Virtual environment thrive

In the light of recent pandemic COVID-19, clinical trials were cancelled or were put on hold. In person doctor visits became virtual and that's where the virtual conduct of clinical trials gained the momentum. Specifically for Pragmatic clinical trial, which is conducted during primary care.

It was one of those times where we could discover how various branch of science could coordinate and work well, so that society in large could benefit from the advanced technological innovations.

Examples of PCTs in Virtual Environment

During the COVID-19 pandemic, digital strategies and decentralized approaches allowed for the continuation of weight loss clinical trials despite in-person engagement coming to halt.

The university of South Carolina led study contactless online group based behavioral weight loss program – by capturing body weight measurements electronically through a Bluetooth enabled smart scale. As a result , patients were independently and continuously able to track and share their outcomes, minimizing trips to the doctor's office.

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The most successful weight loss clinical trials of the COVID-19 pandemic took advantage of decentralized, digital approaches to continuously engage participants during social distancing and lockdowns. These trials delivered interventions such as counseling, exercise classes, diet regimens, and intensive behavioral therapy (IBT) through remote mediums including video conferencing, mobile apps, social media outlets, and phone calls. While many trials focused on shifting existing interventions to virtual platforms, the most innovative trials experimented with novel digital pivots to tried-and-tested therapeutics. For example, the University of South Carolina-led study "Exploring Optimal Treatment Components for Contactless Online Group-based Behavioral Weight Loss Program (iREACH)" modified an intervention previously demonstrated as effective—combining synchronous group-based social support with asynchronous discussion board-based social support—by capturing body weight measurements electronically through a Bluetooth-enabled "smart scale."

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As a result, patients were independently and continuously able to track and share their outcomes over the course of the intervention, minimizing unnecessary trips to the doctor's office.

Likewise, the ongoing Mayo Clinic-led study “Anti-Obesity Phentermine-Topiramate Extended-Release Pharmacotherapy vs Placebo Among Patients Using a Wearable Activity Tracker” utilizes classic weight loss medications in conjunction with VitalCare, a digital health platform and wearable tracker that allows investigators to remotely collect weight, exercise, and calories data and allows subjects to correspondingly document medication compliance. These digital approaches extend traditional research methodologies of measuring discrete, well-defined outcomes at key moments to truly measuring data in real-time across a broader range of metrics and encouraging bidirectional, instantaneous communication between patients and investigators.

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Digital approaches employed by weight-loss RCTs during COVID-19

Exploring Optimal Treatment Components for Contactless Online Group-based Behavioral Weight Loss Program (iREACH) (Remote)

- Combines synchronous group social support with asynchronous discussion board social support
- Provides detailed feedback on dietary and physical activity self-monitoring records from a counselor
- Captures weight via a Bluetooth-enabled “smart scale” with no in-person contact

Anti-Obesity Phentermine-Topiramate Extended Release Pharmacotherapy vs Placebo Among Patients Using a Wearable Activity Tracker (Remote)

- Leverages VitalCare, a digital health platform that allows remote collection of data from the wearable tracker and digital wellness devices used in the study
- Allows subjects to document study medication compliance
- Facilitates remote visits through a video conference between subjects and appropriate study team members

Conclusion

I would like to conclude by saying that there's no one size-fits all solution in clinical trials, incorporation of digital health technologies- such as mobile devices, mobile apps, remote monitoring devices and online social engagement platforms into study design has proven benefits. Improves trial participant recruitment and retention, aids in measuring real-time clinical end points and continuous tracking of adverse Events.

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References:

ncbi.nlm.nih.gov

science direct

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