IMPLEMENTING AN AGILE CLINICAL TRIALS PROCESS

Where do you start?

Gather a strong, multi-disciplinary team.

Pull together a clinical team to design your study. Bring healthcare design experts and user experience professionals into the room to help you ideate on other metrics that will help you find new impact measures, especially in the health outcomes area.

Choose clinically relevant data end points.

Select the right data points by looking at patient reported data, environmental data, behavioral data, claims data, and other EMR data to gather a full picture of patient care. Then define the critical data endpoints for measuring drug safety and efficacy.

Select data collection devices and "one-click-away" patient support services.

Look for best-in-breed, easy-to-use devices that collect data passively and incorporate solid and immediate human support. Assess if the devices will produce medical grade data, and confirm that the results will be reproducible with an acceptable margin of error.

Design an acquisition and recruitment plan using digital tools.

One of the biggest challenges for the pharmaceutical industry is finding patients to enroll in clinical trials. Consider leveraging social media and keywords to recruit potential patients or research subjects "in the wild".

Build a platform for that data.

You'll need a platform that is capable of ingesting data from multiple data sources, clinical interfaces, and connected devices, even if they have different data standards. The key is turning this raw data into something uniform and usable.

Incorporate an analytics engine with preventative and prescriptive capabilities.

By analyzing and collating the information gathered, you should be able to create insights, like whether or not a patient is at an increased risk for a health episode. This enables you to set up alerts for predicted risk factors so the care team has time to react.

Create a rules engine that can trigger alerts and push automated content.

Based on patterns of risk in patient profiles, you can create rules to push content to that patient, prompting them to change their behavior in a certain way. This could be as simple as an SMS alert, but when those risks show up, there should be a repository of content in your system to allow for an automated, educational response.

Design an insights dashboard.

Patients are usually monitored by a team of health professionals, not just by one person. Sit down with different members of the care team to talk to them about what data is most crucial for them, personally, to see on an insights dashboard. Personalized design is king.

Expand patient outreach capabilities to adjust treatment plans.

You can't disconnect the idea of a patient from the human being behind those data points. This is what patient support programs are all about: creating a unified experience which allows the patient to independently make decisions, but also ensures that someone from the care team is available to validate alerts and provide real assistance at any time.

Conclusion

This data-heavy, agile system will allow for a more personalized, patient-centric clinical trial process for each piece of research, and for each patient. It will allow us to determine the efficacy of a drug more quickly than ever before, and at lowered costs.

So... what are we waiting for?

Based on the series: **"Transforming Clinical Trials with Digital Solutions"**

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