Innovation in Clinical Research

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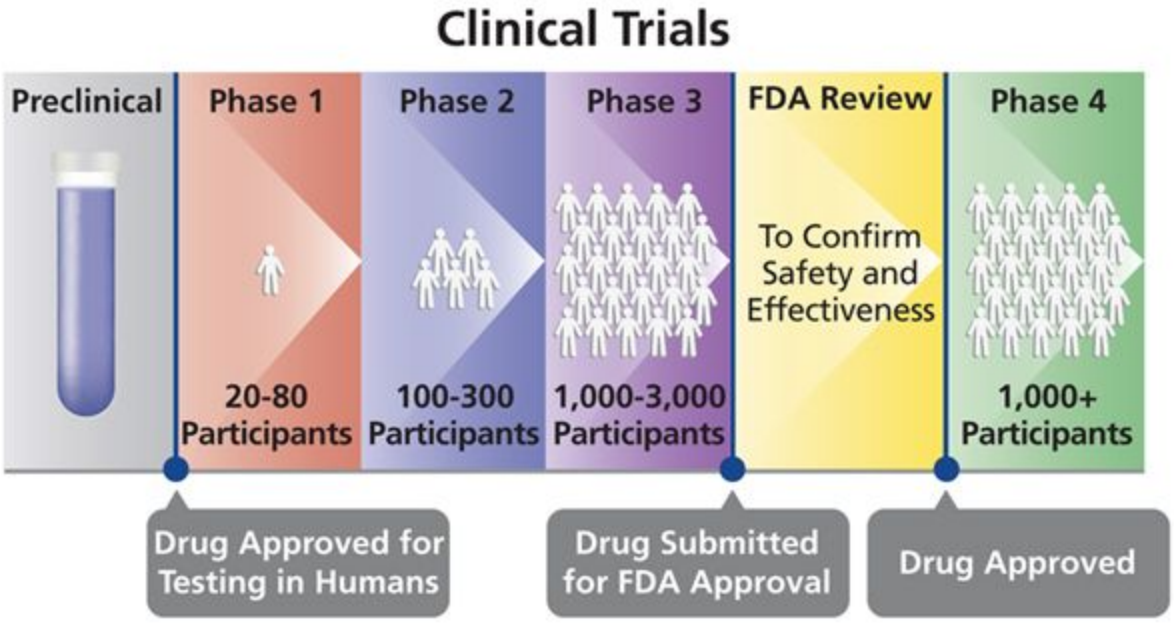
Dr Williw Muehlhausen talked to us via a video presentation about Clinical Research and innovation in this area. Dr Muehlhausen has been working with CRO's (Clinical Research Organizations) for many years and was previously the head of innovation in one such CRO. This is very relevant at the moment with the current coronavirus outbreak and Dr Muehlhausen used this as an example throughout his presentation.

Clinical Trials

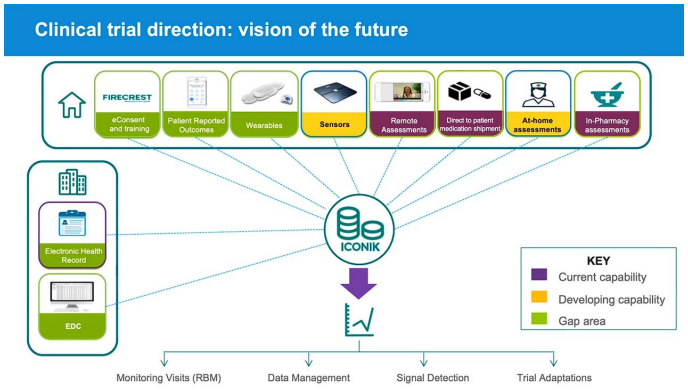
Clinical trials are the process of testing new drugs or vaccines before they are deemed safe for the public and widespread use. First, they are tested on animals before being tested on humans and this is where clinical trials come in. Clinical trials come in phases where more and more testing is done to ultimately find out how safe a certain drug or vaccine is. There are hopes that a coronavirus vaccine will enter phase 1 of clinical trials sometime this year.

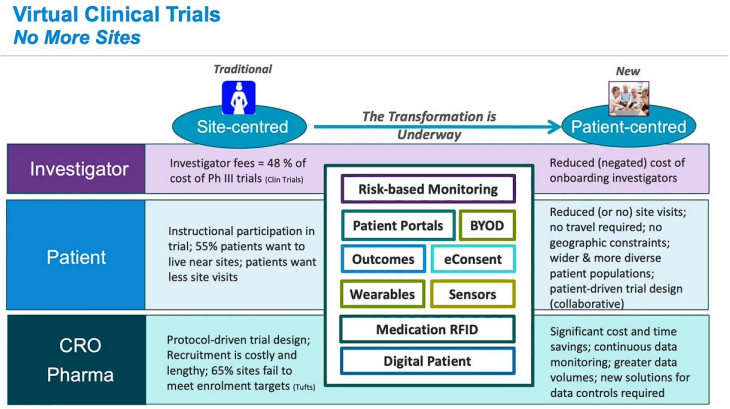


Here is a diagram showing the different phases of clinical trials, and you can see how slowly but surely a drug is assessed/tested and eventually approved for mass use on patients.

Virtual Clinical Trials

Dr Muehlhausen talked a lot about the idea of Virtual Clinical Trials and this will affect the future and certain aspects that have already been implemented. One such aspect is the idea of remote assessments with a patient's GP, via video calling for example. This is already very popular and even more so with the coronavirus outbreak. Other aspects of this that are currently in use include direct-to-patient medication shipment, sensors for gathering data, and at-home assessments also.





The focus on all of this is to ease the patient's burden when undergoing a clinical trial. In the past, patients have to visit a doctor very often for prescriptions and assessments but now patients can take part in a clinical trial mostly from the comfort of their own homes.

Challenges

Currently, only a few of the above-mentioned aspects of virtual clinical trials have been implemented. Of course, new technologies have challenges and the rapid development of technologies such as machine learning and advancements in data analytics have helped immensely.

Research Challenges & Strategy

Challenges	Strategy
Changing device and vendor landscape	Monitor existing and emerging vendors via Consortia (i.e. HealthXL, Wearable Technology AG)
Medical device vs. consumer device	Ongoing Research project to determine validity of data from consumer products
"New" endpoint development	Work with network in Academia to use existing knowledge to support POC projects
"Raw" actigraphy data files are massive	Testing technologies that allow us to analyze raw data in the "cloud"
Signal detection	Ongoing Research project with our inhouse data analysts to develop a procedure to detect signals
Operationalization	Use our eCOA PMs who have experience with Actigraphy projects and work with Validic and Medidata for data processing and storage
Lack of Standardization	Potential collaboration with German TUEV on data standardization Establishment of an Actigraphy Vendor Consortium similar to the ePRO Consortium

One challenge in this field is a lack of standardization, and Dr Muehlhausen spoke of this and how there are plans for a group to come together to help combat this thankfully. Other challenges include new endpoint development, and the ever-changing device and vendor landscape.

Final Thoughts

Overall I found Dr Muehlhausen's presentation very interesting, and the topic of clinical trials and how they work is fascinating to me. It is clear that these are very important in advancements in the medical industry, especially at times like these with a novel deadly virus wreaking havoc on the world.

This sector obviously has a huge impact on the world and the health of the billions of people on earth. Improvements in this area to help speed up and make clinical trials easier will only benefit society as a whole and the improvements we currently see in this sector are amazing to see.