Innovation 2020 - Clinical Research

Willie Muehlhausen

In this blog I will briefly discuss the correlation between Clinical Research and Innovation in the pharmaceutical and Health industry.

Clinical Research

According to Muehlhausen, a Clinical Research organisation is a company that provides services and technology to pharmaceutical, biotech and medical device companies to conduct clinical research.

These Organisations test drugs in people with different issues to see if they work. These issues can vary between a cold or flu to the more current, Coronavirus (COVID-19).

For more on Coronavirus visit:

- https://www2.hse.ie/coronavirus/?gclid=CjwKCAjw3-bzBRBhEiwAgnnLCrXlxTsOFoBfx7LSIrf4yTZudFMxFWorxLq20NK4hRQxjyUmcX4CHhoCAKUQAvD_BwE

Applied Innovation

Famous Ice Hockey Player Wayne Gretsky once said, “I skate to where the puck is going to be, not where it has been”. This simple quote says we should be ahead of the game. As innovators we need to make predications. Without a doubt, there is huge risk and ambiguity involved but innovation is all about talking risks and doing opposite to “The Norm”.

Wayne Gretsky also famously quoted, “You miss 100% of the shots you don’t take”. As stated already although there is huge risk involved, we sometimes must just shoot our shot. We must try things. Yes. we could fail, but we must learn from that failure.

Clinical Trial Direction: Vision of the future

According to the World Health Organization (WHO) Clinical trials are a type of research that studies new tests and treatments and evaluates their effects on human health outcomes.

Clinical Trials are administered after new drug or vaccine is developed. Clinical trials are done to animals, just to ensure the drug or vaccine is safe for humans. After animal testing the drugs and vaccines are tested in humans. There are 4 phases to clinical trials.

For more information of the stages of clinical trials visit:

- https://www.who.int/health-topics/clinical-trials/#tab=tab_1

With the ongoing Pandemic of Coronavirus, these clinical trials will soon be administered. Predications suggest some time in the next few months. Hopefully they can be accelerated to an earlier time.

In the process of clinical trials test-subjects (patients) must travel to hospitals or medical clinics for tests. Nowadays some of these tests can be administered from the comfort of the patient's home. These is done via:

- eConsent and training
- Patient Reported Outcomes
- Wearables
- Sensors
- Remote Assessments
- Direct to patient medication shipping
- At home assessments
- In-pharmacy assessments

Direct to Patient Projects

Sensor technology allows wearables to collect health and wellness data.

Data collection for outcomes research can be reported with minimal invasiveness. This just means patients can be passively monitored. All they must do is just live their life and their health and wellness can be observed.

One challenge to all this is patient privacy. Patient privacy is more paramount now. With the new GDPR Data Privacy Regulations we must make sure we don't infringe on their privacy. Therefore, we must make sure we encrypt the data and store it away, so no unauthorised people have access to it. If the data got into the wrong hands it could be detrimental.

GDPR Data Privacy Regulations:

- https://www.ibm.com/security/privacy?p1=Search&p4=43700050370983606&p5=e&cm_mmc=Search_Google-_-1S_1S-_-WW_IUK-_-privacy%20gdpr_e&cm_mmca7=71700000061224207&cm_mmca8=kwd-357095708617&cm_mmca9=CjwKCAjw3-bzBRBhEiwAgnnLCoez6E6HZ7WRbqeN_Gy8BV4u0sJgDO3sNgXhuukz3JiwGhteFe1M-xoC4jgQAvD_BwE&cm_mmca10=406771686916&cm_mmca11=e&gclsrc=aw.ds&&gclid=CjwKCAjw3-bzBRBhEiwAgnnLCoez6E6HZ7WRbqeN_Gy8BV4u0sJgDO3sNgXhuukz3JiwGhteFe1M-xoC4jgQAvD_BwE

Using Actigraphy in Clinical Trials Today

Actigraphy can be used for people with diabetes or CNS, Respiratory or Cardiology

Actigraphy is used because it is more responsive

- You can ask your patient what symptoms they suffered during the week. Some could explain every detail to perfection but for most people it's hard to remember exactly what happened or what time it happened. Actigraphy devices tell you what is

happening in real-time. It records the time the patient experiences their symptoms.

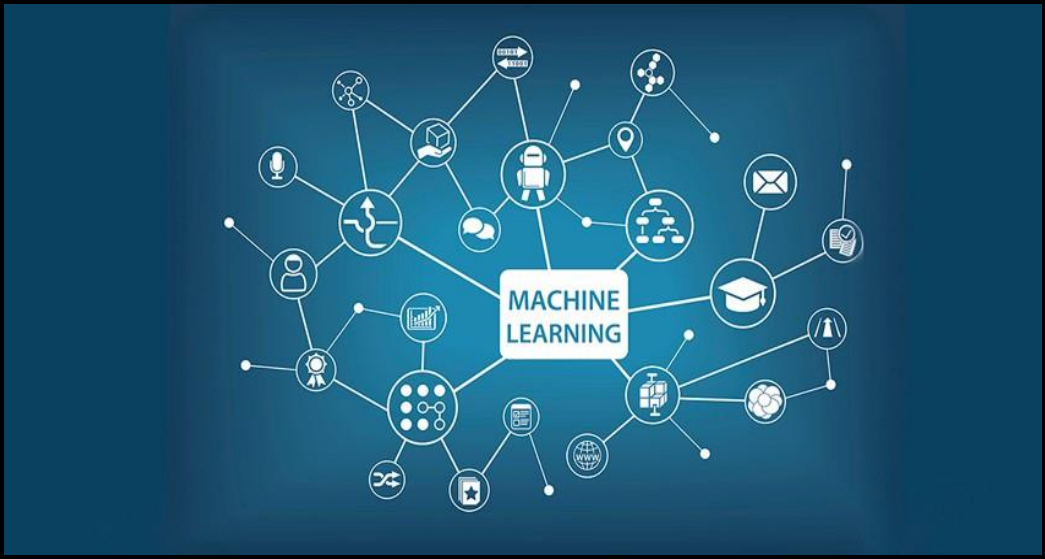
Influencing therapeutic intervention

- We can monitor how much work and movement a patient is doing. If a patient has just undergone surgery and they are moving around a lot, inevitably the pain will be more severe and will last longer. With actigraphy devices this can be monitored my doctors. They can tell the patient exactly why the pain has worsened or is taking longer.

Monitoring sleep

- Actigraphy devices can also help in monitoring patients when while they sleep. We can observe sleep patterns, restlessness, movement etc...

Using Machine Learning to detect Fraudulent Behaviour



The idea of every patient cooperating and complying to the regulations is ideal, but it doesn't always happen. Some patients don't feel like they need to use these actigraphy devices. Some strap the devices onto their animals or give it to their kids or other relatives. Fortunately for the industry these actigraphy devices have been modified to recognise when the main user isn't using the device. For example, these devices can differentiate between the movement of the owner and that of a dog.

In summary, Innovation is very useful in Clinical Research. It makes the work of professionals and patients easier. Regardless of our situation we must keep innovating, keep changing the game. Without innovation we would Liquidate.

By Nicolas Oyeleye