

ACCELERATE CLINICAL DEVELOPMENT THROUGH 4G

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Agenda

- ▶ How things have changed
- ▶ Industrial revolution phases
- ▶ Challenges of pharmaceutical industry
- ▶ Improving efficiency of clinical trials by implementing digitalization
- ▶ Artificial Intelligence in clinical research
- ▶ Virtual and Hybrid clinical trials
- ▶ Cloud computing in clinical trials
- ▶ Mobile technologies in clinical trials

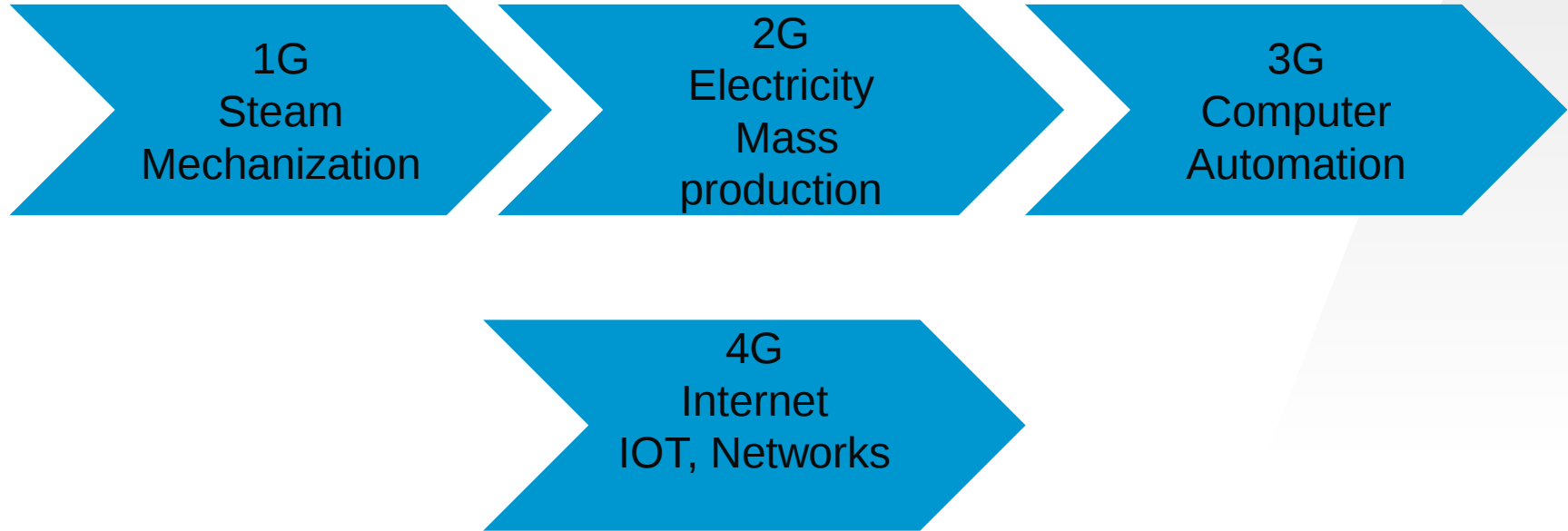
My Story

► How time has transformed....

Earlier it was used to directly walk-in for a Doctor's consultation or Lab test, then waited for a couple of hours to get my turn and complete the procedures.
Now how things have changed..



Industrial Revolution Landing



Challenges of Pharmaceutical Industry

- ▶ Rising healthcare costs
- ▶ Increasing regulatory scrutiny
- ▶ Shrinking product pipelines
- ▶ Expiring Patent rights
- ▶ Economic/Pricing pressures
- ▶ Aging global population
- ▶ Changing customer expectations

Importance of Digitalization in Clinical Industry

- ▶ New class of Digital Chiefs at top Pharma companies – Technology is helping Live longer, healthier, lead safer, more productive lives.
- ▶ As the focus on blockbuster drugs is declining, patient-centricity will be core to Pharma business and digitalization brings convenience, better co-ordination, patient compliance, patient awareness.
- ▶ In 2012, Pharma companies formed the non-profit organization 'TransCelerate Biopharma' to identify and solve common drug development challenges with the end goals of improving the quality of clinical studies by accelerating development of new medicines.

Implementing Digitalization in Clinical Research

- ▶ The goal of a biotechnology company is to develop innovative medicines that demonstrate differentiated treatment opportunities ***while reducing the cost and time to market and maximizing return on investment.***
- ▶ We all aware of that, Pharmaceutical companies spends billions of dollars on clinical trial process. Almost 40% budget was allotted to Pharma research.
- ▶ Here are few of digitalization tools can improve the efficiency of clinical trials
 - Artificial Intelligence
 - Virtual and clinical trials
 - Cloud and Mobile technologies

Implementing AI in Clinical Research

- ▶ By using AI (Artificial Intelligence), we can improve the structure and process of the trials and it will reduce the costs, improve efficiency.
 - Using AI, we can create smarter protocol design.
 - AI can be used to cross compare massive sets of data from past trials to find similarities, areas of concern. Using this we can better tailor the trials.
 - Using AI, we can Improve patient recruitment and retention.
 - AI has the potential to tap patients electronic medical records to cross-reference number of available trials on specific criteria.
 - Assess the probability of good fit, success rates and lowering dropout rates.

Implementing AI in Clinical Research Case Study

- ▶ Drug discovery process → Will consume around 15 years and invest around \$2 billions per drug to get through the market. Chances of making it 1 out of 10.
- ▶ Medical Researchers are dealing with huge amount of new information every day. It's estimated this industry is getting 10,000 new publications per day from biomedical databases and journals → so it's impossible to drill down.
- ▶ UK-based Pharma specialized AI company able to review billions of sentences/paragraphs from millions of scientific research papers/abstracts then develop the links between the data into '*known facts*'. These facts will be curated and generate priority hypothesis by selecting the target disease criteria's which are considered to be worth of exploring.

Virtual and Hybrid Clinical Trials in Clinical Research

- ▶ Virtual clinical trials characterize a method of collecting safety and efficacy data from clinical trial participants, from study start-up through execution to follow-up and increasing degrees of decentralization towards site-less model.
- ▶ If study demands to perform assessments like MRIs, biopsies that cannot take place at patient's home then sponsor can hit upon hybrid design as the best of both worlds. Hybrid trials allow sponsors to reduce the number of sites and processes that enable virtual trials, but still have physical locations to perform certain procedures.
 - Smart phone, fitness watch, wearable glasses will act as a link to clinical study, which will record patient data such as body temperature, systolic-diastolic BP, heart rate, glucose level, ECG readings and sent automatically to EDC.
 - Virtual clinical trials eliminate the cost associated with site selection and clinical research laboratory setup.
 - Pharma companies such as Merck, Pfizer, Novartis, Sanofi are investing in the emerging concept of virtual clinical trials.

Virtual Clinical Trials in Clinical Research Case Study

- ▶ In US, fewer than 5% of Americans participate in clinical trials. Average dropout rate is 30%. Nearly 1/5 of trials are prematurely shut down due to participation shortfalls.
- ▶ US-based top Pharmaceutical company has completed 2 pilot trials.
- ▶ In this trial, 14 healthy volunteers were given Januvia and instructed to periodically draw blood at home through finger sticks and share the sample readings with investigators.
- ▶ Survey stated subjects are comfortable at their homes instead of visiting the sites.
- ▶ Reduces the burden on subjects and investigators.

Cloud Computing in clinical research

- ▶ Cloud computing is not stormy weather 😊

Cloud computing is – On demand self-service, Available everywhere,
Measured services, Dynamic usage.

Benefits of Cloud computing in clinical research –

- Greater study control
- Real-Time reporting
- Access data from any device
- Saves Money and Time

Cloud Computing in Clinical Research Case Study

- ▶ US-based Biopharmaceutical, develops prescription products for aesthetic medicine and facing multiple versions of documents floating in and out as its legacy system was extremely difficult to manage and update.
- ▶ Its quite cumbersome to store, manage and share the thousands of documents internally.

Real-time results of the changeover to cloud computing -

- ▶ After protocols authored by the medical writer are uploaded, the requisite six or seven reviewers are automatically notified.
- ▶ The system is able to alert team members before documents expire.
- ▶ CRO partners have access to clinical trial reports so they are better able to report back on trial status.

Mobile Technologies in Clinical Research

- ▶ The use of mobile technology in all walks of life has become commonplace, it is estimated, mobile penetration stands 96% globally.

Benefits of Mobile technologies-

- ▶ Mobile technology helps to engage with patients and collect their data during clinical trials
- ▶ Communicate with patients i.e. sending reminders to ensure timely actions such as clinic visit attendance, fasting, correct medication intake
- ▶ Reducing the burden on patients by decreasing or even eliminating follow-up visits to research centers
- ▶ By accessing to the stored information allows healthcare providers and trial participants to gain additional insight to disease
- ▶ PatientsLikeMe – online patient community – Members 6,00,000+

Conclusion

The world is going digital, and the digital transformation in healthcare is already in full swing. Let's embrace it, drive it and make it a revolution to the benefit of patients and customers around the world.

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Questions





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