OTTO & COMPANY
STRATEGY CONSULTANTS

Digitalization of clinical trials

Opportunities and Benefits

April 2020

Digitalization of clinical trials bears high potential for both patients and pharmaceutical companies

Opportunities and Benefits

Digitalization Opportunities

Facilitate participation for patients
Enable virtual trial participation from home/ de-centrally, develop appropriate apps for interaction with other study participants

Digitalize clinical trial data management
Harness and utilize digitally or electronically collected and submitted patient data in all clinical trial phases

Improve technology support and monitoring systems
Use advanced data analytics and visualization methods to convert mass into smart data and utilize digital technologies for data collection

Enhance networking effects and patient engagement
Establish new interaction models to improve participant experience and provide platforms for patients to share thoughts and ideas

Secure data integrity and validation
Make sure that critical health data of the patients is secure and protected and that trial results are not demonstrated to the participants

Grow a digitally empowered workforce
Establish a value-based operating model and train workforce to become more flexible and dynamic, expanding existing digital competencies

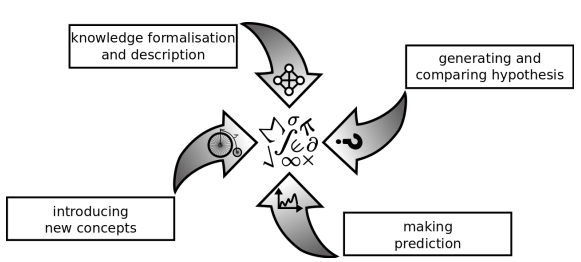
Potential Benefits

- ✓ **Higher patient-centricity and convenience through accessibility, reduced burden for participants**
- ✓ **Improved time and cost efficiency for trial execution**
- ✓ **Facilitated recruiting of patient for trails and enhanced patient retention**
- ✓ **Better and earlier detection and interpretation of product errors and risks**
- ✓ **Improved decision-making during clinical studies based on real-time data opportunities**

Examples of digital capabilities across the clinical trial phases offering significant benefits

Digital Capabilities

TRIAL DESIGN

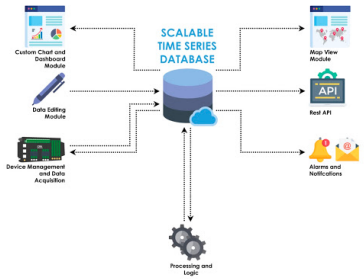


Evidence-based modelling
Using real-world data in the modelling and design phase of the trial

Patient-centric protocol design
Facilitating participation and reducing administrative burden

Early-stage risk assessment
Identifying risks for patients early based on available data from other trials or sites

TRIAL SET-UP

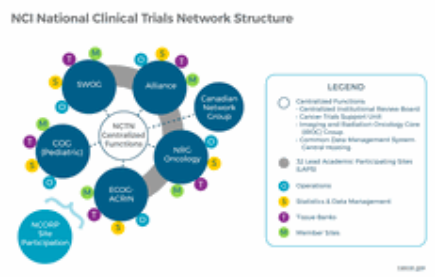


Digital patient platforms
Providing information regarding trials on platforms for interested patients and selecting data-driven

Digital monitoring systems
Setting up appropriate infrastructure to coordinate and monitor trials and study groups

Digital/ electronic site set-up
Increasing set-up speed and automating supply chain

TRIAL EXECUTION



Digital data collection
Using wearables and digital tools to collect real-time data

Technology-based analysis
Setting up interfaces to collectibles for interim data analytics (Big Data)

Patient adherence platforms
Establishing patient-centric adherence and networking platforms

TRIAL EVALUATION

Enhanced data visualization
Creating dynamic and flexible dashboards for trial results

Digital stakeholder communication
Submitting trial results to authorities electronically and initiating review online

Digital patient engagement
Giving thanks and trial data to patients individually online