Technology & Clinical Trial Innovation

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EXPECT EXCELLENCE

ADVANCING DRUG DISCOVERY AND DEVELOPMENT

PPD®

Innovation?

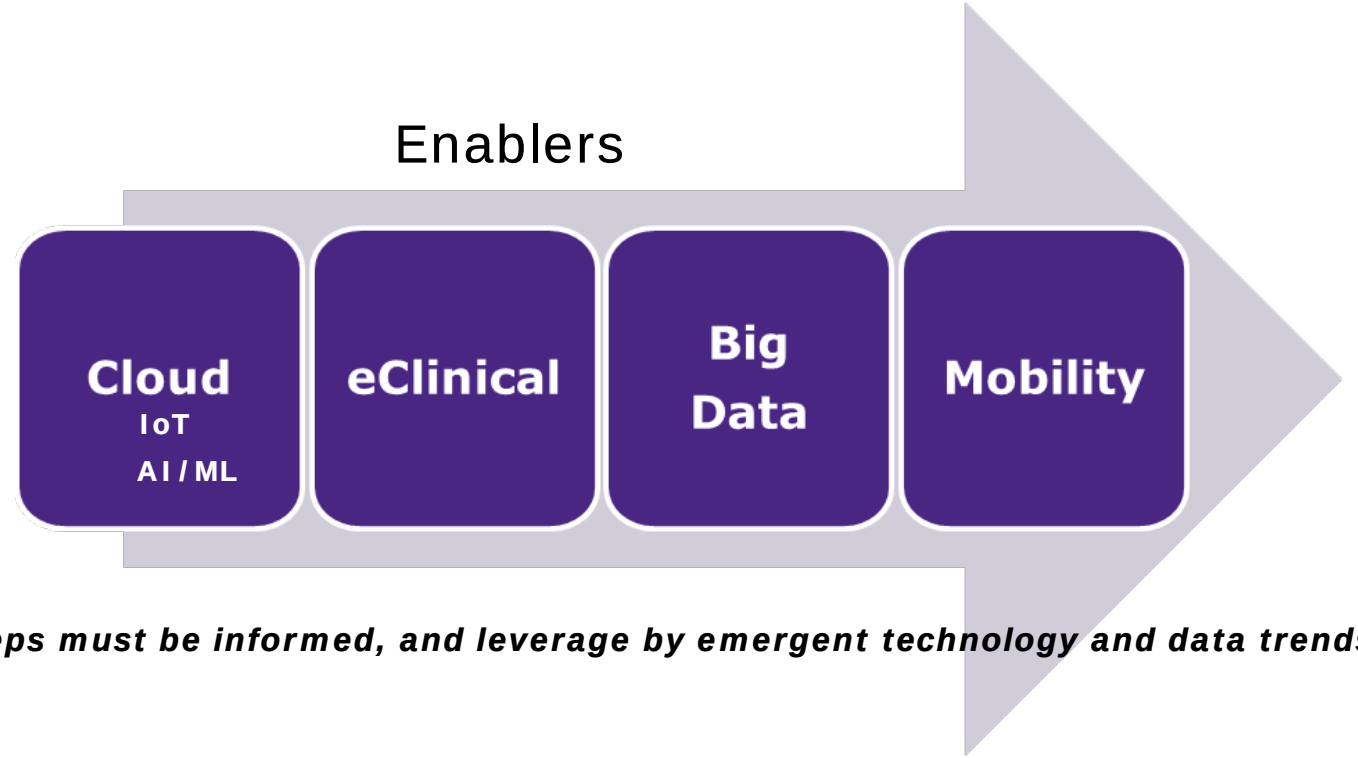
‘do different’

innovate

make changes in something established

Life Sciences Trends

- Patient Centricity
  - Personalized medicine/pharmacogenomics
  - BYOD and Wearables
  - Patient outreach and enrollment

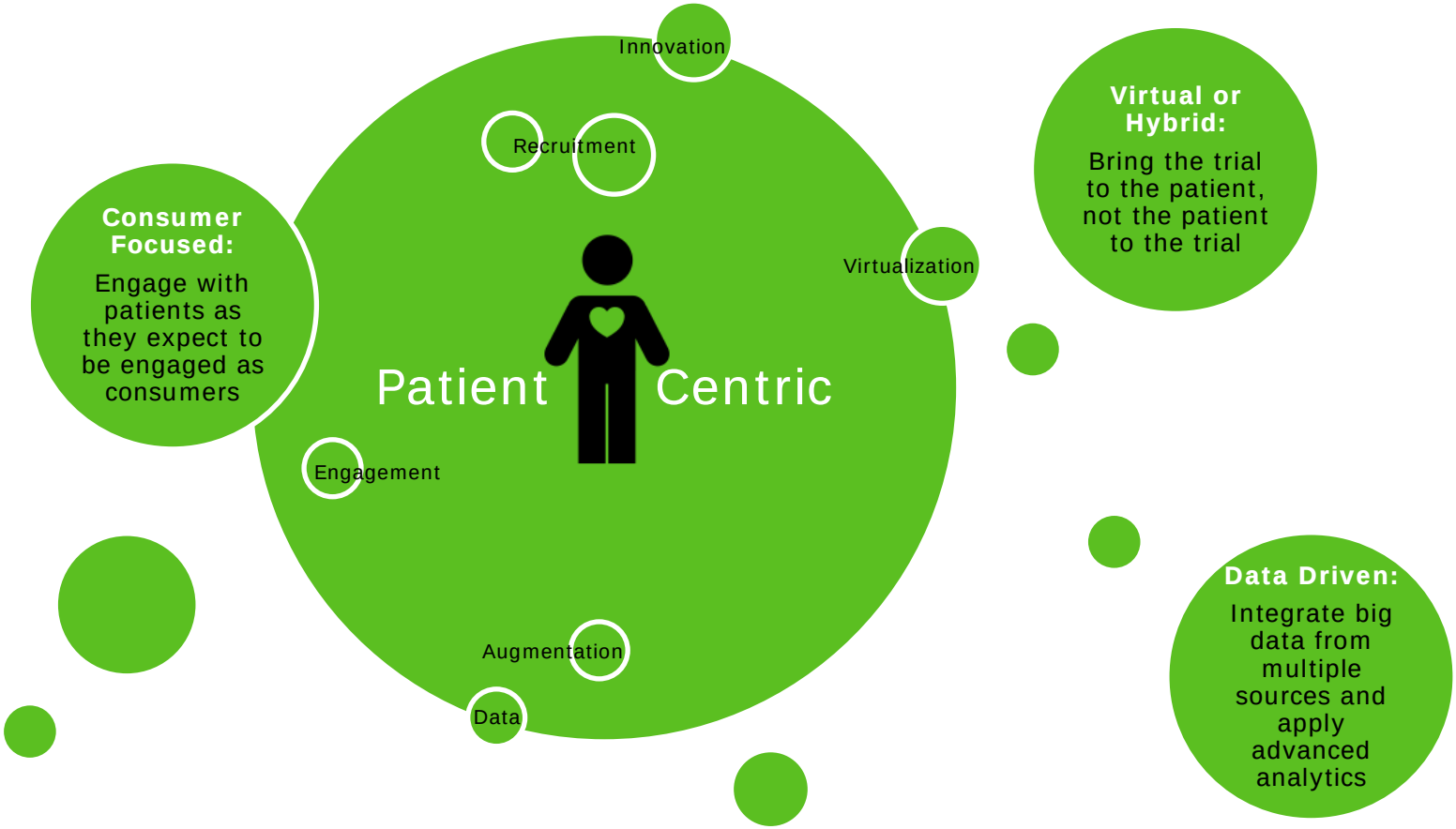


Our next steps must be informed, and leverage by emergent technology and data trends

Business Driven Technologies

Patient-Centric Trials

+ How we leverage new thinking to overcome the inherent conservatism and risk aversion in a highly regulated industry to drive innovation and transformation



Virtual Trials

What is a virtual trial?

Traditional trial	Virtual trial
Patient visits the site (hospital) to participate in the trial.	All data is collected virtually or in the home, making life convenient for the patient. Minimizing site visits to only those that are not feasible in the home or remotely.
Site is usually a large academic medical center, in major city center.	Reduction of all or nearly all sites in a country to one “virtual site.”
All diagnosis, dosing and tests are performed at the site making life convenient for the doctor but not the patient.	Requires centralized / remote “ownership” of the patient by the doctor and study coordinator at the virtual site.
Most sites only enroll small number of patients, so we need a lot of sites.	

What are the key benefits?

More patient-friendly trial designs	Reduce burden on patient; improve study recruitment & retention
Access to broader patient populations	Increase enrollment rates, bring research to more patients
Use of connected devices and software to conduct trials wherever the patient is	Higher quality data / Reduced monitoring costs

Why is this important to patients ?

121 minutes
Average patient spends traveling and waiting to see doctor

15 minutes
Average time an in-person visit takes

5 minutes
Average telehealth wait time

More than 80% of participants said they would be more willing and able to participate in future research studies if they could do so remotely.

Virtual Trials

How will we do it?

+ Bring the trial to the patient
+ Using TECHNOLOGY and new/additional services
+ We will fundamentally shift the center of the research from the site to the patient's location

How do we spot a good opportunity for virtual trials?

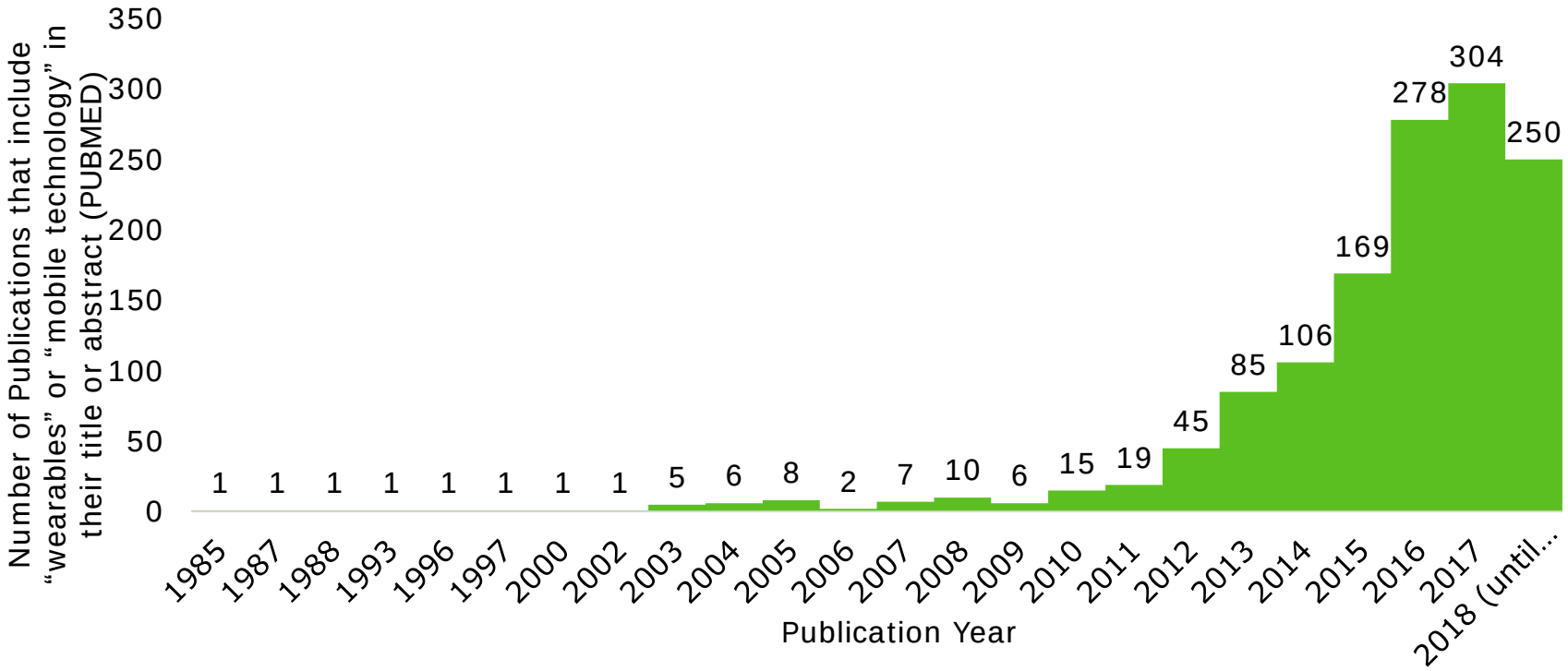
TAs that are amenable to **Virtual Trials** include:

- Rare diseases
- Respiratory
- Dermatology

- Disorders with medical self-management that can be treated at home
- Indications that can be diagnosed remotely
- Assessments / data that can be collected remotely
- Studies with high site pre-screening costs

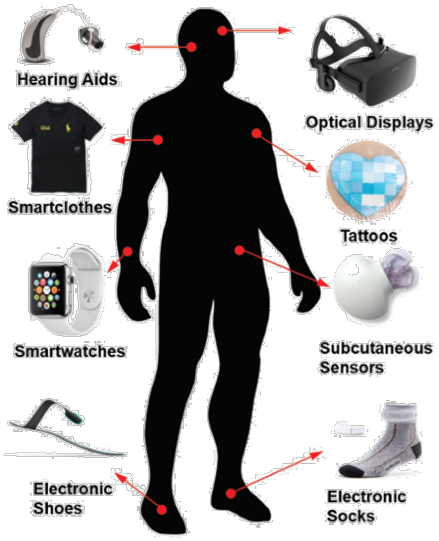
Academic Publications on Wearable Technologies

The number of publications on PUBMED that include ***"wearables"*** or ***"mobile technology"*** in their title or abstract have risen rapidly in the past few years

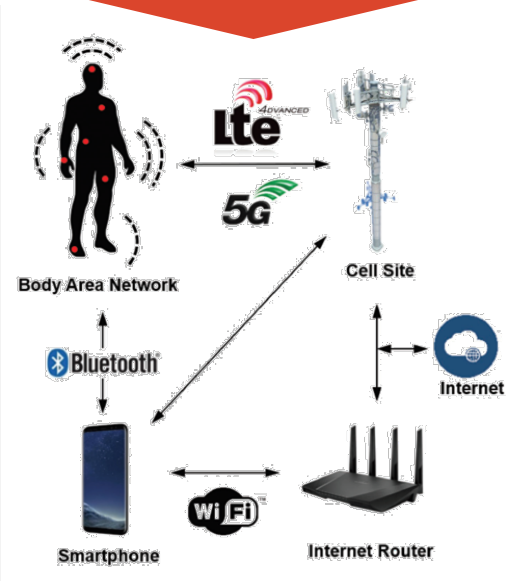


Wearable Technologies

Wearable technologies include smartwatches, wristbands, hearing aids, electronic/optical tattoos, head-mounted displays, subcutaneous sensors, electronic footwear, and electronic textiles[1]



Data collected from wearables is transmitted to the internet through Bluetooth, Wi-Fi, LTE, 3G, 4G, or 5G connection for further analyses or feedback from a healthcare provider



[1] Yetisen AK, Martinez-Hurtado JL, Ünal B, Khademhosseini A, Butt H. Wearables in Medicine. Adv. Mater. 2018;30(33): 1706910.

Wearables in Clinical Trial Research

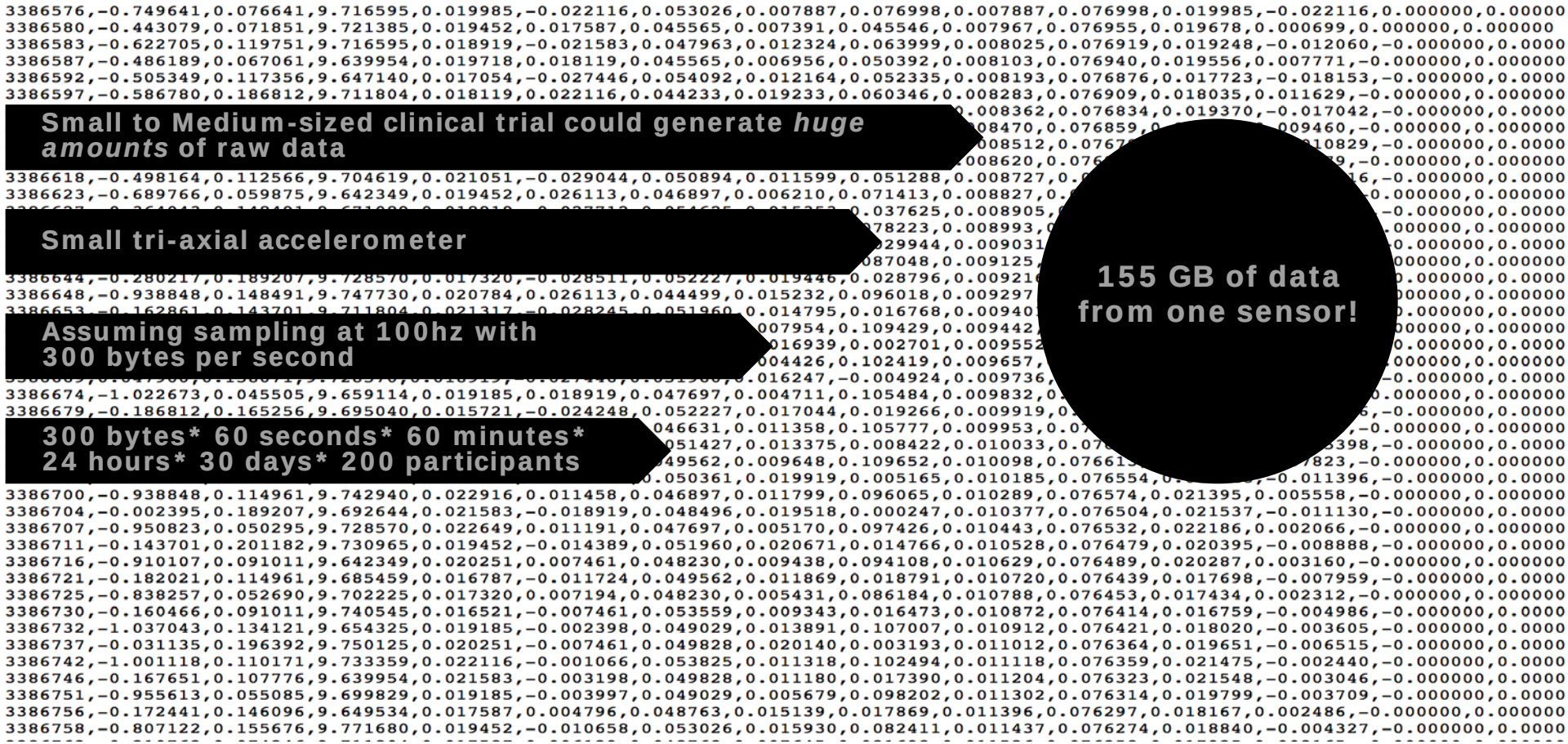
BENEFITS

- Can be used for multiple disease indications
- Increases measurement precision
- Reduces patient burden
- Allows continuous data collection over long follow-up period
- Patient compliance

CHALLENGES

- Device selection and validation of device for context of use
- No standard regulatory guidelines for implementation
- LARGE amounts of data produced
- Placebo effect
- Patient compliance

A few seconds of raw data from a single accelerometer!

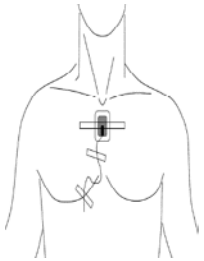


HELPING DELIVER LIFE-CHANGING THERAPIES

PPD

Innovation in Action
Wearables

+ A company is developing a compound to treat chronic cough
+ The primary objective of the pivotal trials is to evaluate the efficacy of gefapixant in reducing cough frequency measured over a 24-h period[1]
+ Trials are using the VitaloJAK® system for objective measurement of cough frequency
  - 24h ambulatory digital sound recording device, developed to count coughs
  - Only medical device with FDA 510K approval and CE marking currently available for the capture of ambulatory cough

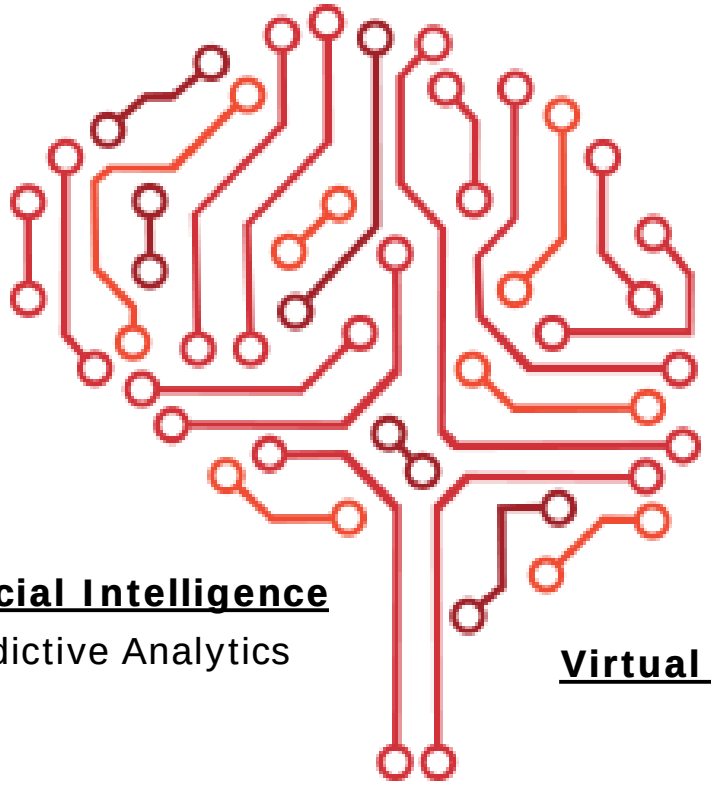


  - After sounds are acquired, data are processed in Vitalograph's centralized reading center, where human analysts identify and tag individual coughs

[1] https://clinicaltrials.gov/ct2/show/NCT03449134

Intelligent Automation Capabilities

Center of Excellence -> Innovation Accelerators



Robotics

RPA

Chat-bots

Machine Learning

Real World Data

Safety

Artificial Intelligence

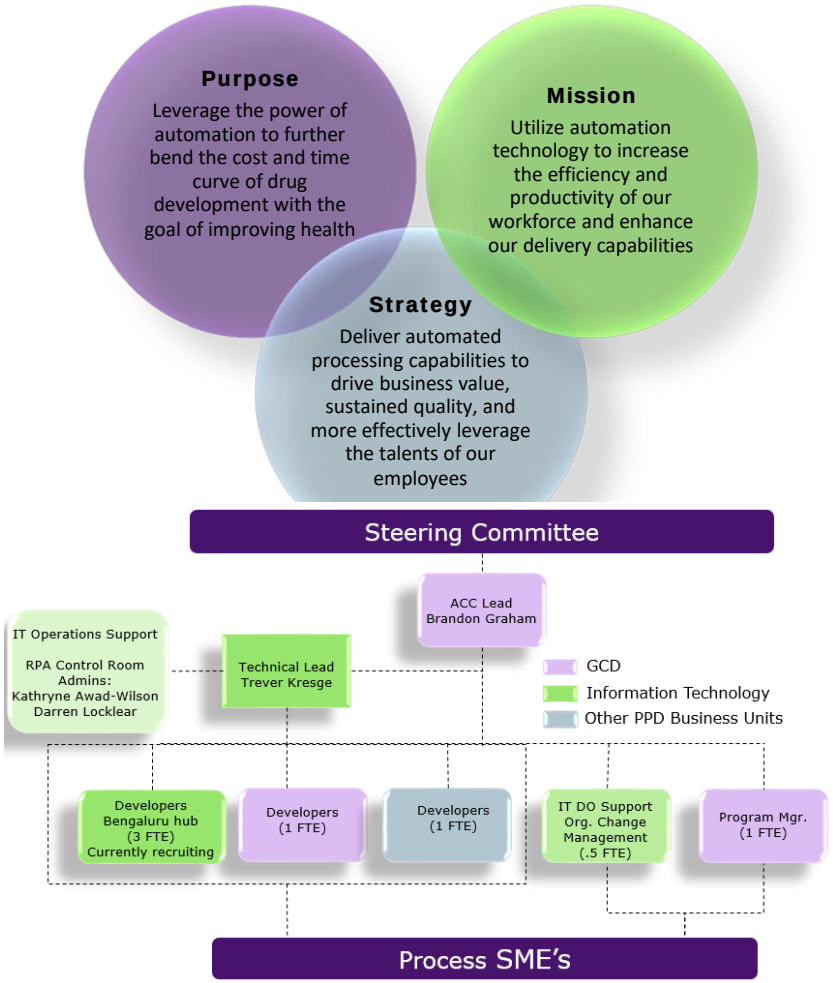
Predictive Analytics

Virtual & Augmented Reality

Gamification

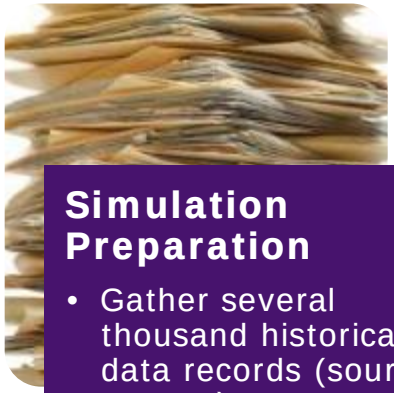
Innovation in Action
Robotic Process Automation

- RPA
  - Software programmed to handle high volume, processing work
  - Reduces burden of repetitive, simple tasks
- PPD platform: Blue Prism
- Automation Capability Center
- 2018 - eTMF automations
- Goal: > 10 automations fully implemented in 2019



Innovation in Action
Machine Learning

+ PPD partnered with SAS to introduce Machine Learning technology to Pharmacovigilence
+ Machine Learning platform was capable to developing the algorithms (machine learning) by reading historical reads and predicted the next data sets with very high degree of accuracy (>95%). Moving now to implementation with a customer.



Simulation Preparation

- Gather several thousand historical raw data records (source reports)
- Collect results data set that links to source reports.
- Log serious verse non-serious case designations

Learning Data Set

- Machine reads half of the raw source reports and results data.
- Machine Learning generated algorithms based on know results to predict future data sets
- Process leverages algorithms to determine serious/non-serious on unknown cases

Test Data Set

- Machine reads second half of the data sets through the ML without the serious/non-serious results
- Generate predicted result data set using (ML) Machine Learning using statistical algorithms.
- **Machine was >95% accurate**

? QUESTIONS ?