Balancing the thrill of innovation and the fear of humiliation in choosing technology for CNS trials

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Disclosures

- Employee of Boehringer Ingelheim Pharmaceuticals, Inc.
  - The views expressed in this presentation are my personal opinions and not those of Boehringer Ingelheim Pharmaceuticals, Inc. Content of this presentation may not reflect current legal or regulatory requirements, industry standards, or professional best practices.

Objective

- Practical & operational considerations in CNS trials
  - Medication adherence monitoring
  - Exploratory biomarker data collection

Integrating innovation in clinical trials is like an iceberg...

WHAT OTHERS SEE:
Successful implementation of innovation

WHAT IT TAKES:
- Risk
- Education
- Rejections
- Persistence
- Hard work
- Criticism
- Flexibility

Challenge:
Ensuring medication adherence in patients with schizophrenia?

Solution:
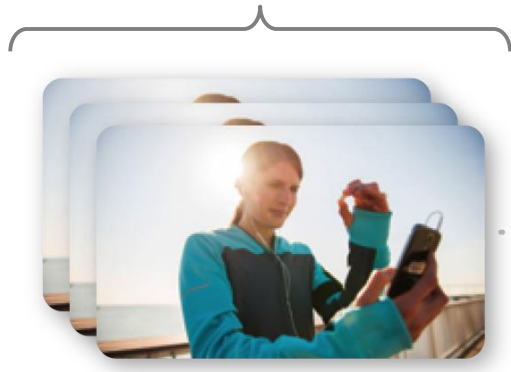Artificial intelligence platform

Smartphone-based AI application

- Artificial intelligence
  - Facial recognition, study drug identification, ingestion monitoring
- Dosing reminders
- Clinic visit reminders
- Micro-reimbursements
- Instructions and support
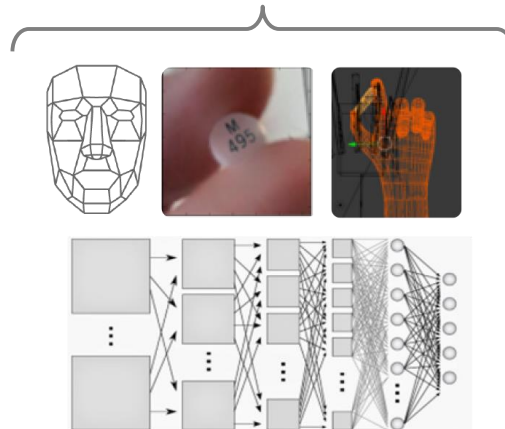- Fraud detection
- Date/time of each dose

Using AI to monitor ingestion

Input from Device

Computer vision & Deep learning

Output on Dashboard

Learnings and considerations

- Internal and External acceptance

- Legal review

- Data privacy concerns

- Informed Consent language

- Ethics Committee approval

- Technical/connectivity issues

- **Communication, appropriate timeline estimates, proactive engagement**

Reasons for adoption

- Accurate data for primary measure of adherence
- Real time data for Sponsor and site staff
- Retention/engagement tool – micro-reimbursements

Challenge:
Operationalizing exploratory biomarker data collection and analysis

Solution:
Help from internal stakeholders, outsourcing to vendors
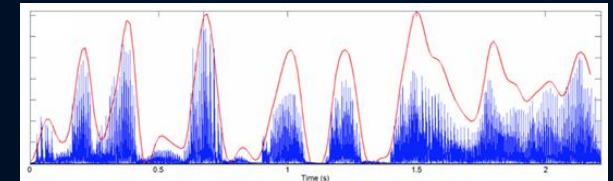
Exploratory biomarker - speech analysis

- Audio-recorded interviews –Standard passages, dream reports/memories, positive images

- Audio recordings and transcripts analysed

- Potential for a novel scoring algorithm for automated speech analysis that could be used as part of the psychiatric evaluation of patients
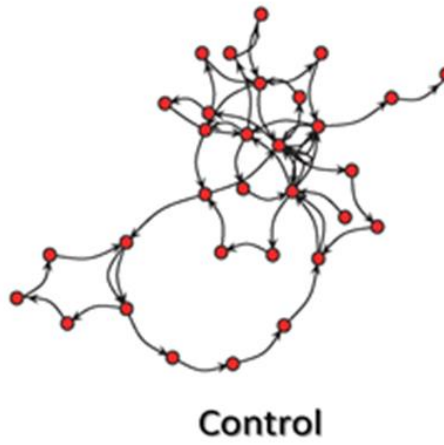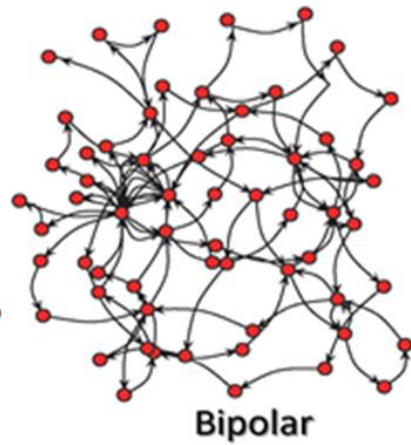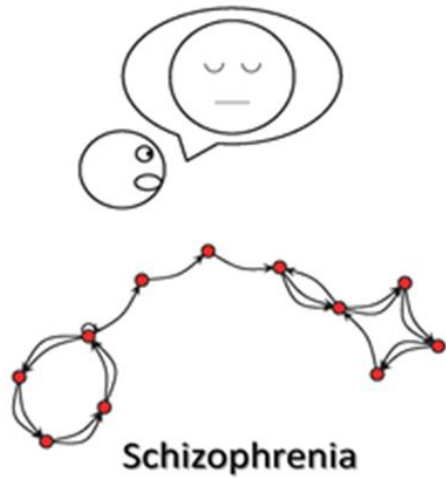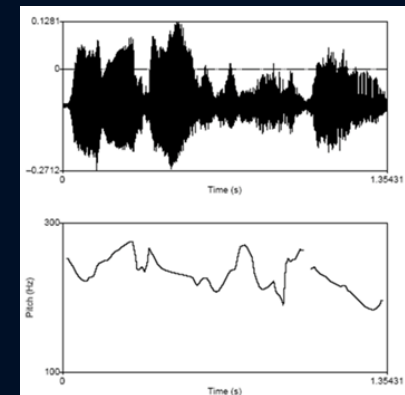
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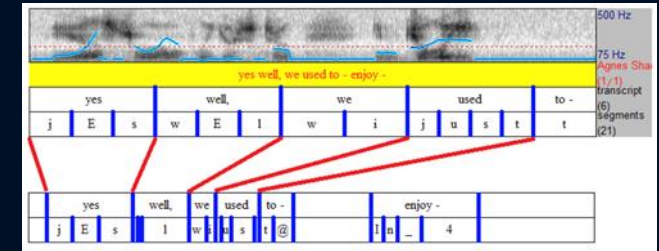
Rate and Rhythm

Prosody

Interviews recorded using laptop and supplied recording equipment

Encrypted audio files uploaded to amazon S3 platform and downloaded vendor server.

Vendor uses laptop with the decryption algorithm to access the files for transcription. Audio and transcription files will be transferred to...

Speech analysis scientists access the data and perform analyses via HITRUST Cloud Platform

HITRUST Cloud Platform

Learnings and considerations

- Supplying audio recording equipment.

- Transcriptions

- Translations - verbatim or acoustic

- Site tools/patient friendly guides

- **Operationalization**

- Data privacy – voice recordings are PHI

- Cloud platform for data analysis
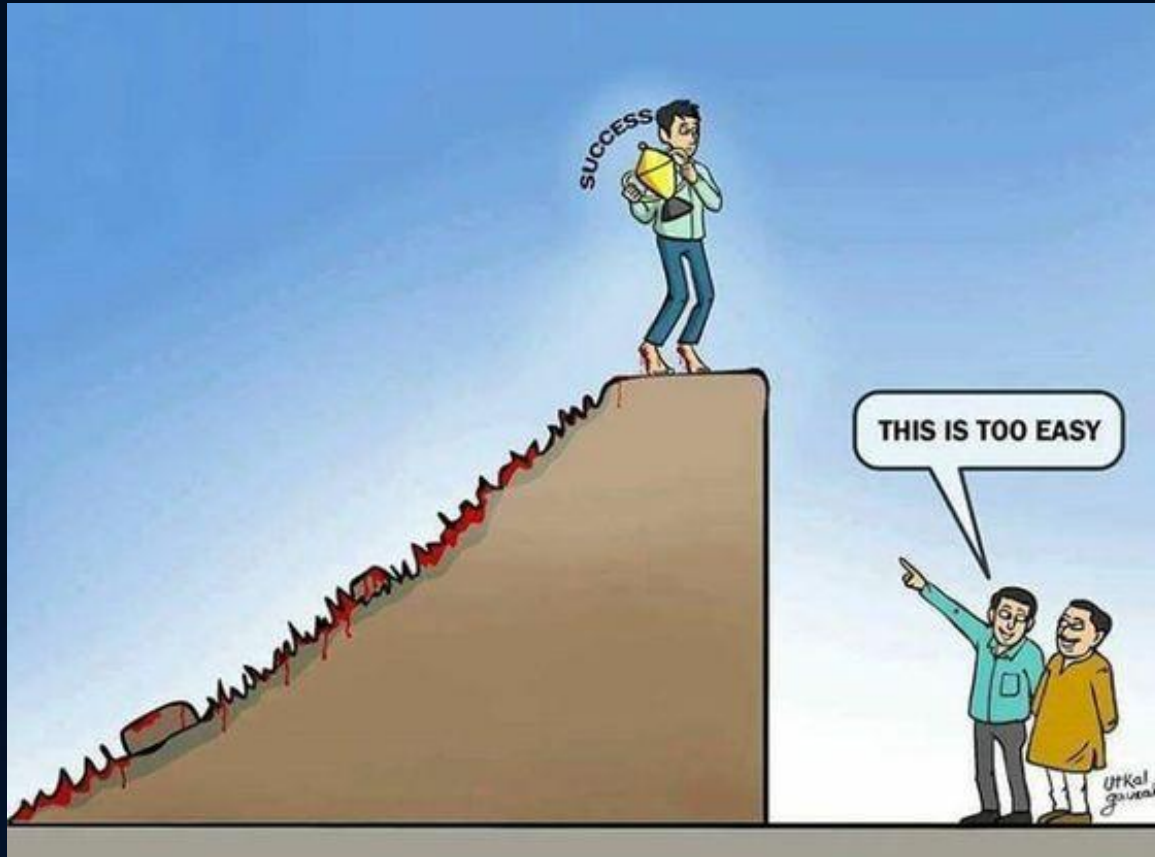
- **Appropriate timeline estimates and proactive engagement**

Reasons for adoption

- Relatively simple data collection
- Potential for advancement of novel biomarker

- Including innovative new technologies in clinical trials can seem very simple

- Be prepared for significant challenges, and a great deal of work behind the scenes.
- The time and effort are well worth the potential advancement of science and data quality.