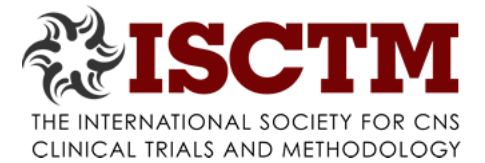

ISCTM ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING WORKING GROUP

ISCTM AUTUMN MEETING, 7 SEPTEMBER 2019, COPENHAGEN, DENMARK



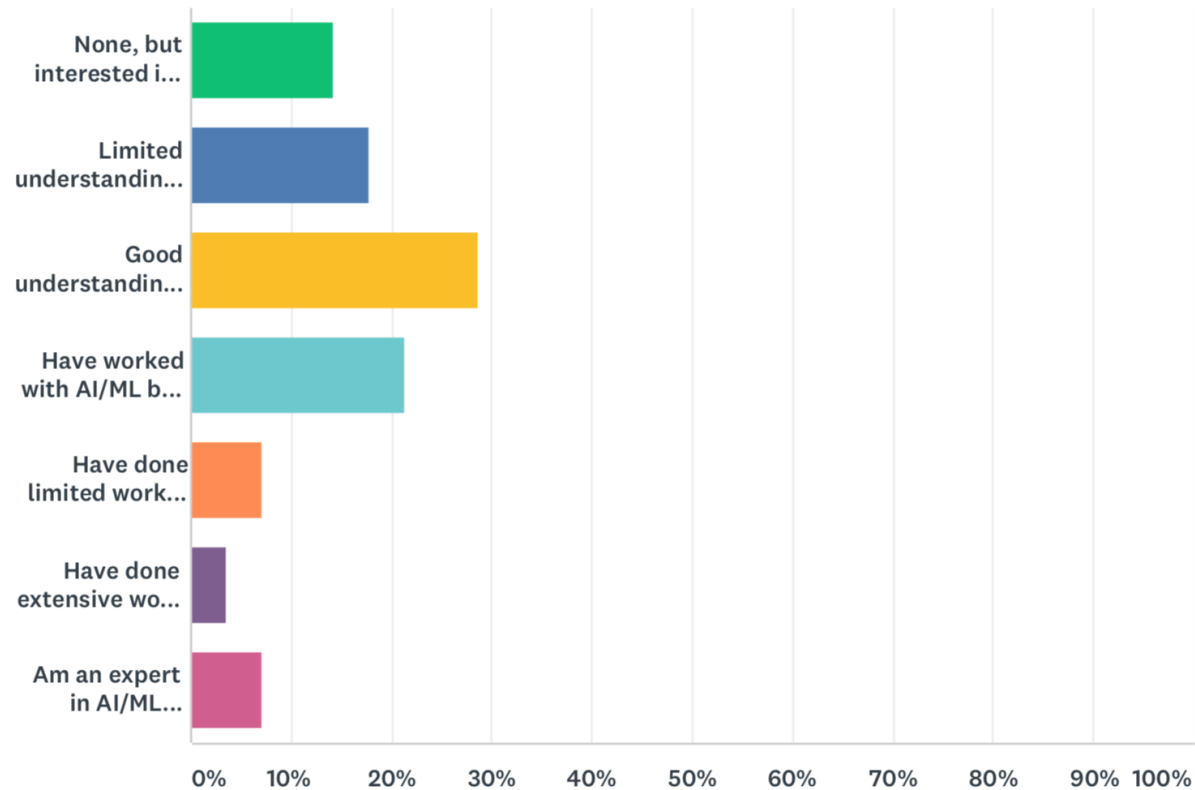
AI AND ML WORKING GROUP AGENDA

- Poll results from our member survey
- Review the FDA discussion document and our response
- Discuss the program for February symposium
- Group discussion regarding a WG deliverable

WG SURVEY ON AI/ML

Q3 Indicate your expertise in Artificial Intelligence/Machine Learning (AI/ML):

Answered: 28 Skipped: 0



WG SURVEY ON AI/ML

- “Monitoring of efficacy of COAs in clinical trials”
- “Predictive analytics using structured and unstructured data”
- “Gene expression biomarkers in psychiatric disorders”
- “Use of AI for diagnosis and/or disease progression of CNS disorders”
- “Development of applications to improve signal detection in clinical studies of CNS drugs”
- “Use of RWE to supplement clinical trials”



Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)

PROPOSED REGULATORY FRAMEWORK FOR MODIFICATIONS TO ARTIFICIAL INTELLIGENCE/MACHINE LEARNING (AI/ML)-BASED SOFTWARE AS A MEDICAL DEVICE (SAMd). FDA, APRIL 2019.

“EXAMPLE HIGH-VALUE APPLICATIONS INCLUDE EARLIER DISEASE DETECTION, MORE ACCURATE DIAGNOSIS, IDENTIFICATION OF NEW OBSERVATIONS OR PATTERNS ON HUMAN PHYSIOLOGY, AND DEVELOPMENT OF PERSONALIZED DIAGNOSTICS AND THERAPEUTICS.”

PROPOSED REGULATORY FRAMEWORK FOR MODIFICATIONS TO ARTIFICIAL INTELLIGENCE/MACHINE LEARNING (AI/ML)-BASED SOFTWARE AS A MEDICAL DEVICE (SAMD). FDA, APRIL 2019.



ENHANCING CNS DRUG DEVELOPMENT THROUGH AI AND MACHINE LEARNING

- What is AI, Saeed Ahmed, Biogen
- Using Machine Learning and Neural Networks to Predict Placebo Response, Joe Geraci, Netramark
- AI and ML Applied in a Trial, Jane Tiller, BlackThorn Therapeutics
- AI-enabled Digital Phenotyping as a Vehicle for Improved Clinical Trial Qualification, Dennis Wall, Stanford
- FDA Discussion on Statistical Issues Related to AI and ML

AI AND ML WORKING GROUP DELIVERABLE

- What are the key obstacles to exploring AI and ML?
- Which clinical trial problems would be best helped with AI and ML?
- Work Product for WG

AI AND ML WORKING GROUP DELIVERABLE

- What are the key obstacles to exploring AI and ML?
 - Statistical Issues
 - Clinical Trial Issues
 - Regulatory Issues
 - Payor Issues

AI AND ML WORKING GROUP DELIVERABLE

- Which clinical trial problems would be best helped with AI and ML?
 - Concrete, first-hand examples of how AI has helped at institution?
 - Which unresolved challenges would be best addressed using AI and ML?
 - Strengths
 - Limitations

AI AND ML WORKING GROUP DELIVERABLE

- Work Product for WG
 - What would members like to see in a white paper?
 - Who can commit time?
 - How much time?

MEETING MINUTES 7-SEP-2019 WORKGROUP MEETING

- There are a diverse set of experience within the working group, including several who have already taken advantage of AI and ML in the trials processes
 - The majority of the group still has limited direct experience
- Consensus on compiling a whitepaper addressing some of the primary issues
 - It's possible that this may generate enough coverage that multiple papers

MEETING MINUTES 7-SEP-2019 WORKGROUP MEETING

- Ethical considerations are an important consideration. Data ownership, consent, and algorithm ownership all need to be considered.
- The analysis and interpretation of wearable and sensor data is increasingly reliant on AI and ML tools.
- Operational optimization is already being done using historical datasets. Clinical trial site identification, patient identification.
- There have been some successful applications based on RWE. One example given was a Truvan EHR analysis to help determine disease course and predictive models for certain diseases.
- Use of AI and ML to support new outcome development is also an important opportunity.
- Using AI and ML tools to support the ongoing reliability and validity of clinical outcomes in trials is helpful. “Data monitoring”
- AI and ML give us an opportunity to possibly develop “objective” outcomes measures based on better data sets.

MEETING MINUTES 7-SEP-2019 WORKGROUP MEETING

- The working group will focus on 5 key areas for whitepaper development
- **Clinical Outcome Development**
- **Trial Enrichment**
- **Exploring Placebo Response**
- **Companion Diagnostics or Digital Biomarkers**
- **Trial Optimization**