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CENTER FOR GLOBAL CLINICAL RESEARCH DATA

AI/ML Draft Proposed Framework 2.5

December 20, 2024

Proposed AI/ML framework

- The following AI/ML framework has included input from our prior sessions since June and input from our discussions
- We propose a risk scoring framework that takes into account the major categories of risk identified by the group
- Please consider this a Version 2.5 to be refined

Task Group Participants

- Alex Nasr, AbbVie
- Radek Polanski, AstraZeneca
- Janet Krause, Biogen
- Jean Sposaro, BMS
- Andreas Freisinger, Boehringer Ingelheim
- Vishal Goyal, DNDi
- Brenda Baker, Ionis
- Tamsin Sargood, Johnson & Johnson
- Ben Rotz, Lilly
- Mette Gilling Nielson, Lundbeck
- David Leventhal, Pfizer
- Paula Boyles, Pfizer
- Jen O'Callaghan, Roche
- Genevieve Rasiah, Roche
- Lauren Cameron, Roche
- Karin Antoni, Sanofi
- Roman Bobrovsky, Takeda
- Kristi Whiteside/Natalie Julian, UCB

Framework Elements

- Model Type (10 pts)
- Model Data (10 pts)
- Model Usage (10 pts)
- Usage Risk (3 pts)

Element 1: Model Type

Model Type	Risk Level	Examples	Comments	Scoring
Machine Learning Models	**Low**	Lasso, Random Forests, Support Vector Regression, Decision Tree, K-Nearest Neighbors (KNN), Gradient Boosting, Kernal Machine, Boosting, Gaussian Mixture models (GMMs)	Defined models similar in nature to standard statistical models. Used for structured data and low risk of unintended outputs. Interpretable, well-defined models.	+1
Artificial Neural Networks (ANNs) and Similar Algorithms	**Moderate**	Artificial Neural Networks (ANNs), Convolutional Neural Networks (CNNs), Recurrent Neural Networks (RNNs), Transformer Models (non-generative)	Powerful. Some consider these “black box” models due to difficulty interpreting how decisions are made within models. Increased complexity, some difficulty in controlling outputs.	+2
Generative Models / Large Language Models (LLMs)	**High Risk**	GPT, Generative Adversarial Networks (GANs), Diffusion models	Concerns that these may “contain” external data and may allow for identification of complex patterns	+10

Element 2: Model Data

Model Data	Risk Level	Examples	Scoring
Untrained	**Very low**	Model is untrained on any data	+0
Anonymized	**Low**	Model is trained on anonymized data (example clinical trial/registry data that is anonymized)	+1
De-identified*	**High / Not allowed**	Model is trained on de-identified data (example clinical trial data that has identifiers de-identified, pseudonymized)	+10
Identifiable data*	**High / Not Allowed**	Model is trained on identifiable data or large datasets that may have significant overlap with requested data (EMR of large hospital system for example)	+10

* Do not allow as Vivli only allows anonymized data to be imported

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Element 3: Model Usage

Model Usage	Risk Level	Examples	Scoring
Export of model (No)	**Low**	Data is used to confirm that a model is performing as expected, adjust algorithms parameters, or to build custom model using the data in the environment. May take the learnings and create a model externally with other data.	+0
Export of model (Yes)	**High/Not allowed**	Data used to adjust algorithms parameters. The model / algorithm does not need to be exported. Only the parameters for the algorithm may need to be exported and not the model itself.	+10

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Element 4: Usage Risk

Risk Level	Factors	Scoring
Low	• Competitive risk • Trusted researcher (prior track record) • Aims of the research (training of a product, creating an algorithm for publication, patient care, placebo vs. active arm) • Commercial vs. academic entity	+1
Moderate		+2
Higher		+3

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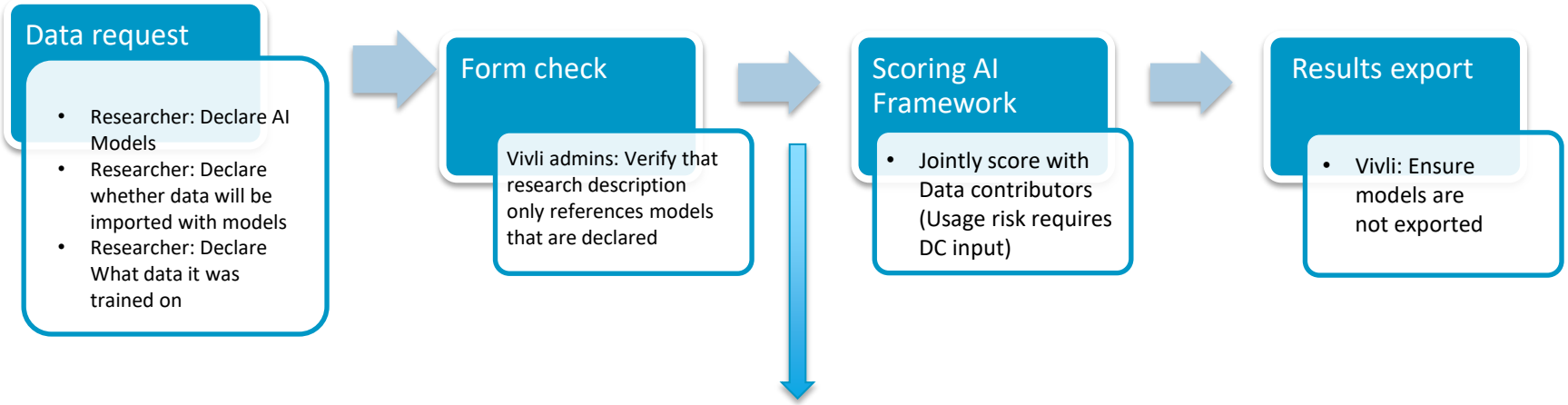
Suggested Risk Level for Framework

- **Lower Risk**: Total score of 4-5
- **Moderate Risk**: Total score of 5-8
- **Higher Risk**: Total score of 8-12
- **Not allowed** 12+ not allowed

Roles for the Vivli AI/ML Framework



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