



A Programmer's Point of View of Current and Future PD Detection Tools

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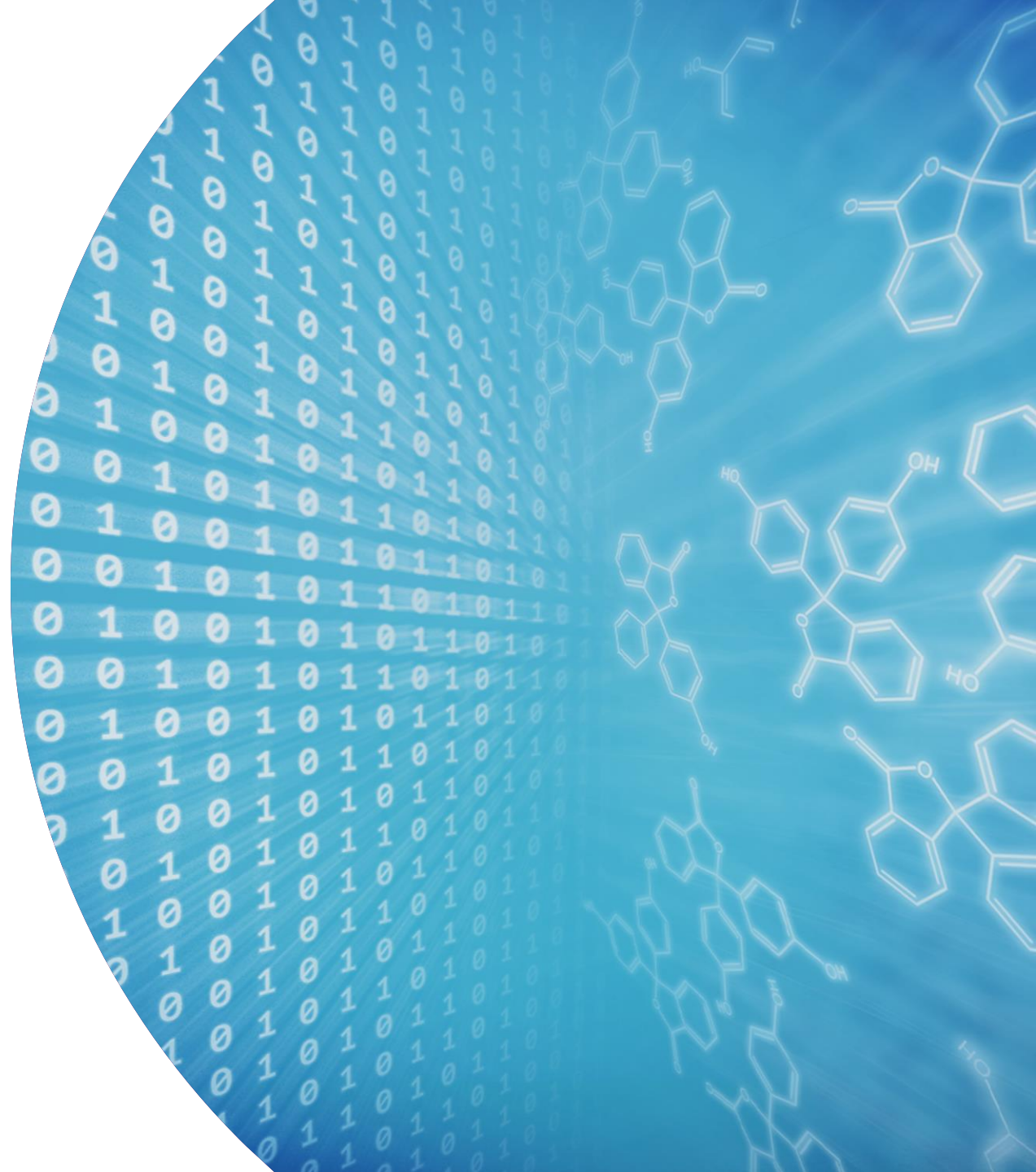
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Overview

- Background information
- Current programmatic approach
- Future approach



Background information

- What is PD?

ICH E3 Q&A:

A protocol deviation is any change, divergence, or departure from the study design or procedures defined in the protocol.

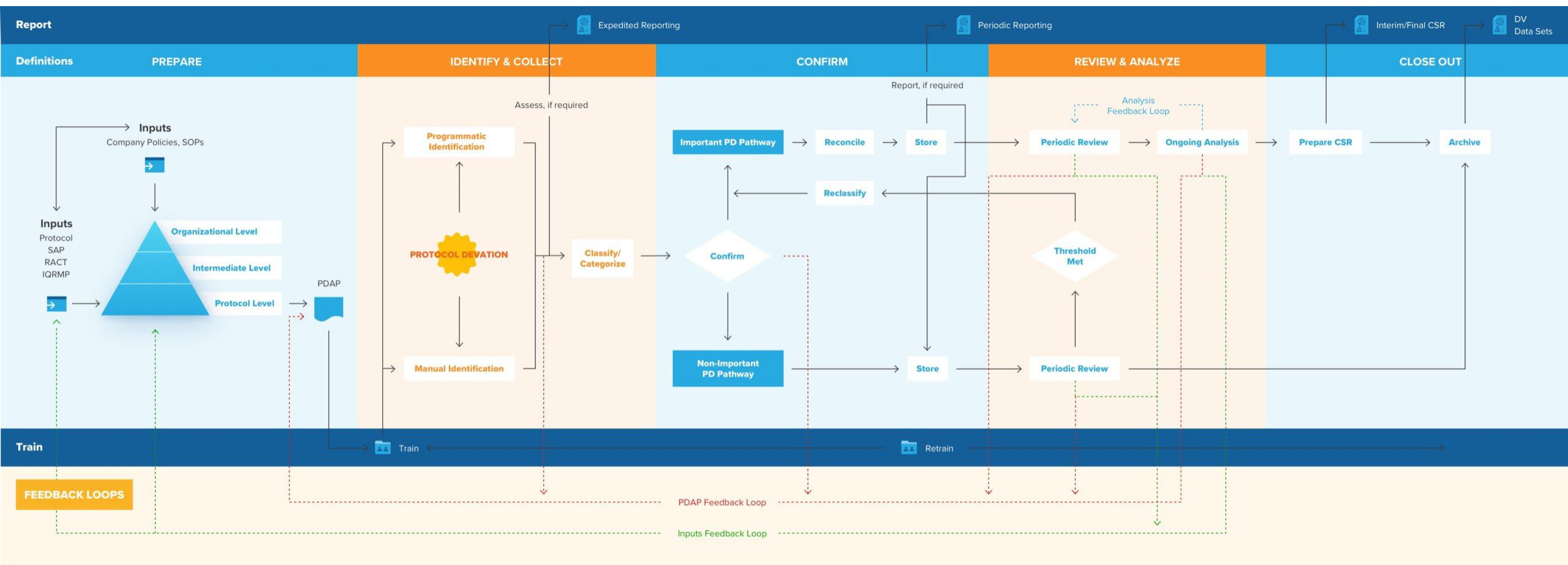
- Detection method:

Manual detection

Programmatic detection

- Statistical programmer's role in the process of identification and handling PD





TransCelerate Protocol Deviation Map https://www.transceleratebiopharmainc.com/wp-content/uploads/2022/08/PD-Process-Map_081222-scaled.jpg



Current programmatic approach

- Traditional ways
 - Macro based tools
- Advantages and Issues
 - Advantages:
 - Reduction in human effort and increase in accuracy
 - Issues:
 - Collaboration across functions
 - Adaptation of tools
 - Programmatic detection combined with manual review
 - ❖ Example:
PD to detect the XXX dose not maintained at the same level from Visit 2 to Visit 3 for reasons other than safety.

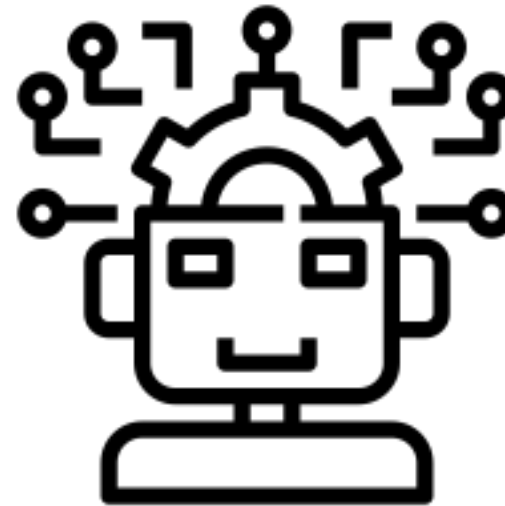


Future approach

- What is AI/-ML?

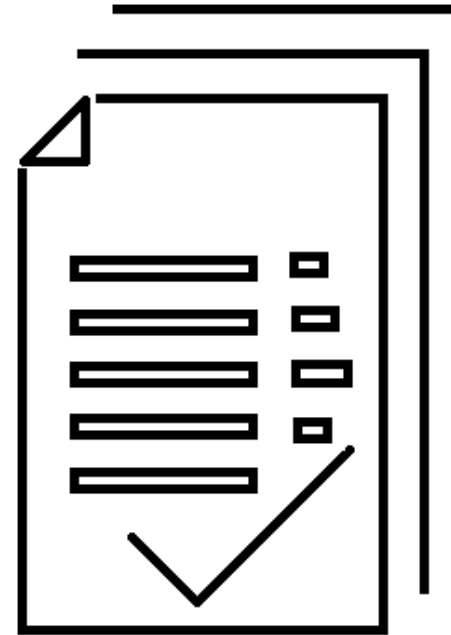
AI 'is a field, which combines computer science and robust datasets, to enable problem-solving.' according to IBM.

ML is a sub and main field of AI. ML is the ability for a machine to think and learn.



Future approach

- Why choose AI/-ML for PD detection?
 - Feature of PD logic
 - Relatively simple logic
 - High quality source Data



Future approach

- Advantages and challenges of using AI/-ML for PD Detection
 - Advantages
 - True automation
 - ❖ Real-time monitoring
 - ❖ Detection of early warning signs
 - Variety of source data
 - ❖ Example: images, documents
 - Paving the way for other statistical analysis
 - Challenges
 - Model training
 - Training data
 - Model fitting
 - Investment
 - Changes
 - Regulation



Questions?



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