

Reactive to Proactive: Scaling AI for Product Health

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Complex Manufacturing Network is a Challenge to Manage Product Health

Complex Pharma manufacturing:

- **101** products
- **12** internal manufacturing sites
- **168** external sites

Example of different product issues:

- **Product A:** raw material supply risk
- **Product B:** loose cap liners were discovered during QC release testing
- **Product C:** a CQA is trending toward the specification limit, increasing the risk of losing batches
- ...

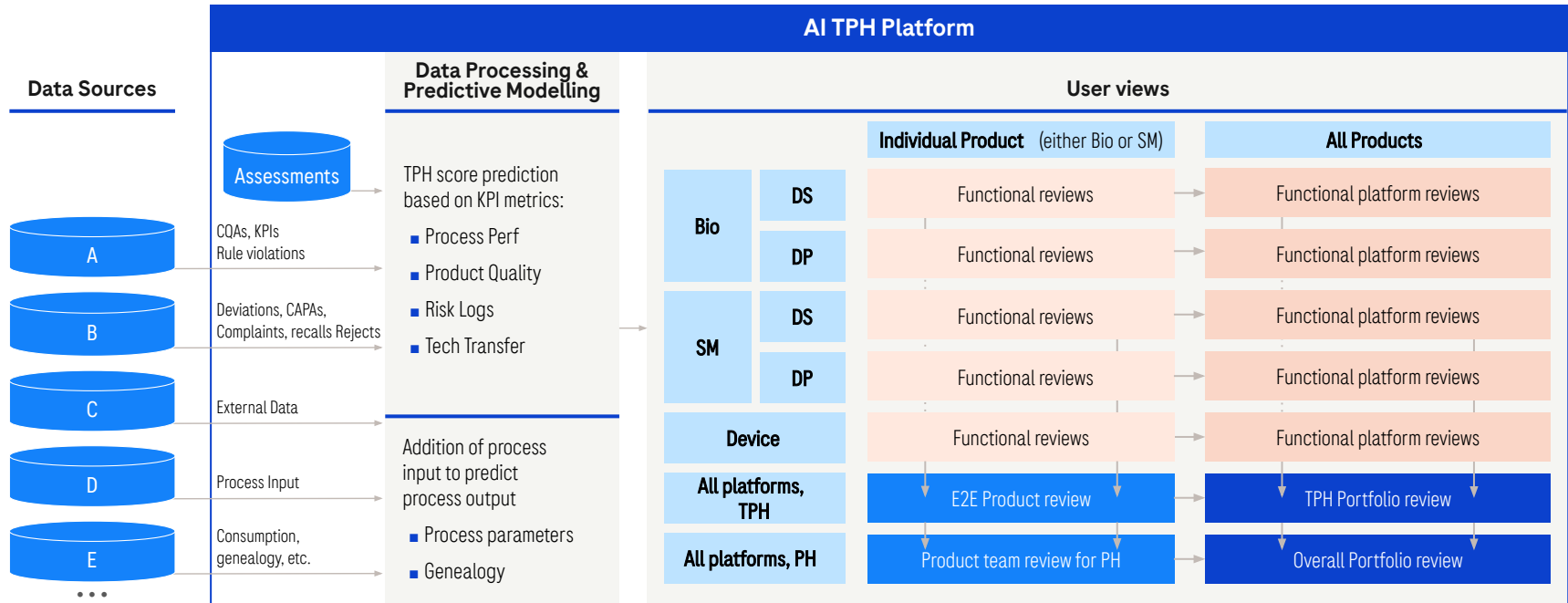
Our Pharma manufacturing network



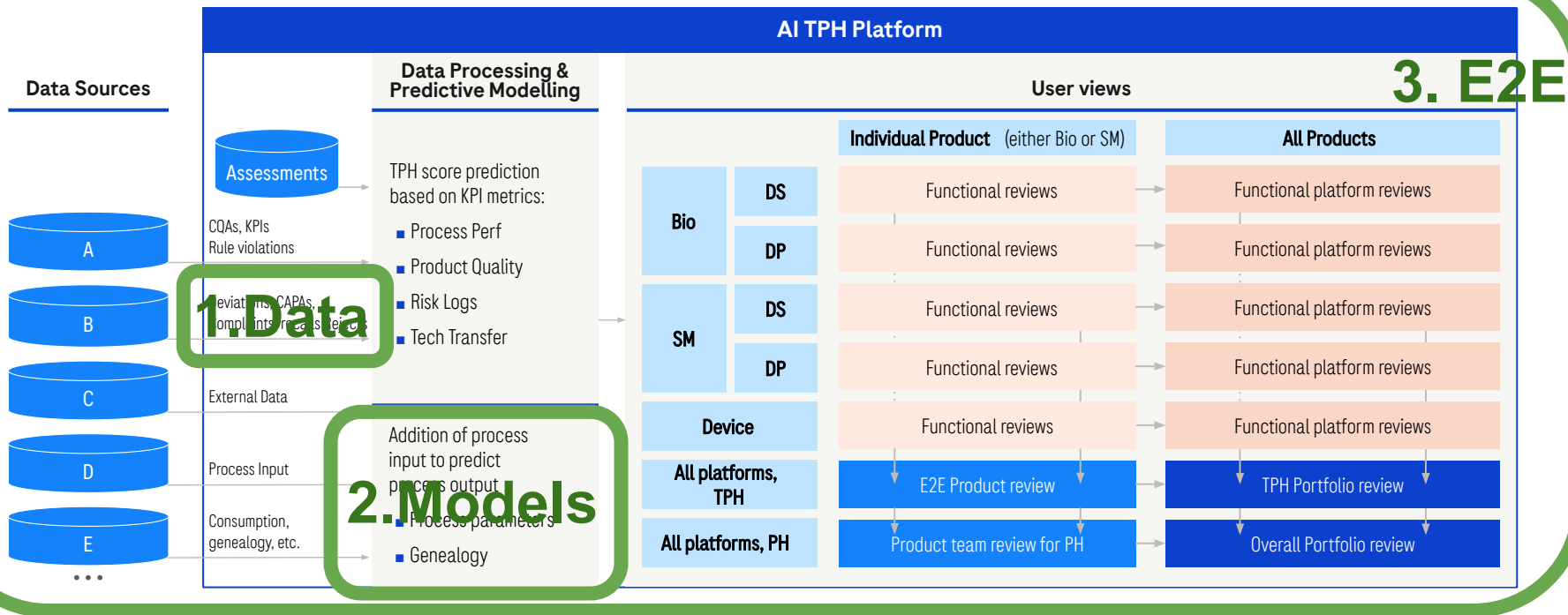
Focus on the biggest opportunity: holistic and proactive Technical Product Health management

Solution: AI TPH Platform Ecosystem

Current focus: Manufacturing (DS, DP, Device) and QC; Development and Packaging and Labelling out of scope



AI Applies to Data Labeling, Process Prediction, and E2E



Where AI
applies

1. Data Relevance

AI labeling for TPH related deviations and complaints, enabling SMEs to focus on what truly matters



Automated Parsing

Automated data parsing, categorization, and contextual labeling.



Eliminate Bottlenecks

Streamlining workflows by eliminating manual tagging bottlenecks.



Structured Foundation

Establishing the high-quality, structured data foundations to power advanced modeling.

✓ **TPH-Related Deviation:** A total of five underfilled ampoules were found. Furthermore, small damages were observed at the bottom of the ampoules.

✗ **Not TPH-Related Deviation:** A critical GxP computerized system is currently experiencing an unexpected outage.

2. Proactive Control via AI/ML models



Scaling prediction models from process inputs to outputs to drive real-time improvement and proactive risk mitigation

Challenge



300+ influencing factors
5-25% yield variability between batches
10 mio data points in predictive models

Solution



Predictive apps provide suggestions to operators:

- a) Optimized batch sequencing based on actual performance
- b) Prediction of exact transfer timing
- c) Process parameter optimization within validated ranges

Impact

10+ products in scope to date
~50% portfolio value covered
200+ models built



Business & patient impact
> 10% titer/yield increase



Proactive risk management
70-90% prediction accuracy

3. E2E Agentic AI

Autonomous orchestration, reasoning capabilities, and context-aware action execution



End-to-End SDLC

Requirements & Design: User story generation & UI/UX design

Data & Analytics: Automated data checks & accelerated analytics

Engineering & Quality:
Autonomous code generation & continuous evaluation



Dynamic Capabilities

Real-time handling of complex, ad-hoc queries from users to enable immediate, data-driven decisions and operational adjustments.

Example: Delivered a fully functional, interactive app within a few days including multiple iterations, which may take months before.



Workflow Orchestration

Autonomous task execution connecting disparate systems and teams across functional boundaries, maintaining strong human-in-the-loop governance.

Organizational shift: Everyone becomes managers - managing AI Agents!

Doing now what patients need next