

PP20: Machine Learning-AI is the future – What now?

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INTRODUCTION

The pharmaceutical industry is investing vast amount of money in R&D to bring ML-AI driven solutions to enhance overall End-to-End Clinical Trials experience. The ML-AI based driven solutions will change the approach to the current new drug-biologics application submissions to the regulatory authorities however they are still costly and will still take some time to become industry standard. What's the plan in the interim? Within clinical data operations, the industry invests heavily on the global data collection standards to enhance the data collection experience, bringing pseudo-automation into the current process. This helps foster consistency within the data collection process, expedite CDISC SDTM compliant package creation and ease the analysis component down-stream. There are tools available that highlight pseudo-automation with expediated quality outcomes which have already been proven effective. Using the cost benefit analysis, pharmaceutical companies can realize that these tools are an investment into their future vision of ML-AI solutions.

PRESENT CHALLENGES WITH R&D OUTCOMES

There is **increasing pressure** on the tools & process:

- Digital solutions present new challenges for research
- New and complex study design and data collection
- Volume and complexity of data types and sources are burdening the system
- The development timelines and the added costs

Existing processes are **inefficient** and **burdensome**:

- Significant time is spent enabling systems
- Most of the actual data cleaning effort often does not result in data change
- Manual review is needed to supplement programmable solutions
- Despite high false positive rate, data issues are caught downstream

Data Complexity and Data volumes are challenging today's business models and driving up the cost of research and development.

- Compared to 2001-05 the average number of data points collected **increased by 88%**.
- Due to the increase in the total number of procedures, costs per patient visit **increased by 34%**.

FUTURE OF CLINICAL TRIALS

As science continues to evolve, innovative therapies will get introduced based on different adaptive study designs practiced in the clinical trial process. The patient-centric clinical development will be the focus of the industry to get more desirable outcomes on the complex study designs. This will require different approaches to manage the clinical data as the patient-centric model will be likely the most disruptive, especially when vastly decentralized. The industry will have to understand the complex data architectures, and scale-up the underlying technologies to evaluate the meaningful operational value from the data.

Per Órlaith Burke (Future of Life Sciences Lead at The Dock – Senior Principal on Advanced Analytics & AI at Accenture), “the research shows that there will be a significant increase in the efficiency and effectiveness of the next wave of clinical trials due to the development of improved technologies, access to real-world evidence and data. This should also increase the industry's capacity to innovate.”

THREE SUCCESSIVE WAVES OF CHANGE:

The **NEXT WAVE** will take advantage of new technologies and start-up inventions.

- 01 Immersed in treatment
- 02 Continuous Patient Data
- 03 Adaptable trials
- 04 Next-gen support eco-system

The **NEAR WAVE** will address the high volume of increasingly complex clinical data sources and connect patients to trials remotely.

- 05 Intelligent Trial Onboarding
- 06 In Data We Trust
- 07 Seamless Data Management
- 08 Stay At Home Trials

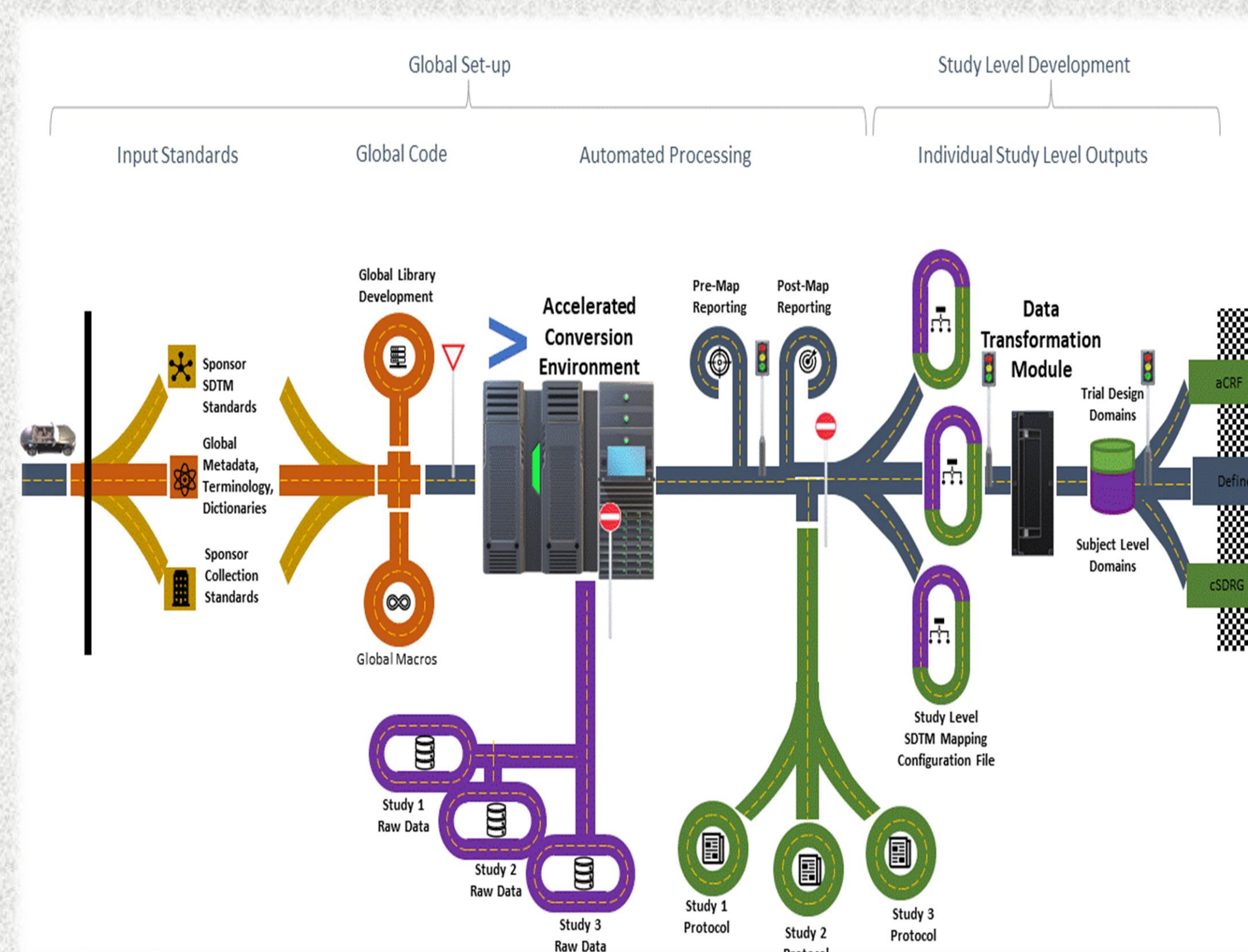
The **HORIZON** indicates a trajectory toward global clinical trials and a potential promised land of patient-free trials.

- 09 Declaration of Data Standards for Global Clinical Trials
- 10 Personalized Trials
- 11 Trial By Algorithm

FOUNDATION PESUDO-AUTOMATION - CDISC SDTM DELIVERABLES

The Accenture CDO group has been able to set a foundation bringing innovative business solution by helping sponsors to bring pseudo-automation using their global standards to expedite CDISC SDTM submission compliant deliverables with optimum quality and consistency. The solution assists conversion activities and provide beneficial tools for developers, to help guide large scale projects for the sponsors. The solution facilitates a proactive approach towards development of CDISC SDTM deliverables. Efficiency, consistency and maintenance via a centralized design control center are key elements to those development benefits. Accenture utilizes global conversion standard libraries provided by the sponsor or produced by Accenture to process and create desired SDTM outputs. Large-scale conversion activities across multiple therapeutic areas require complex data handling, delta reporting abilities for version maintenance and control management to ensure quality sponsor expectations.

The solution can provide a more fine-tuned large global capacity model that can garner greater consistency and establish groundwork for future development and streamlined review and update methodologies. Developing a global MDR lifecycle system to sustain growth, create efficiencies, increase production and produce a turnkey approach to SDTM conversion services. Furthermore, to build a system that can handle development activities, which are beyond the simple scope of an MDR.



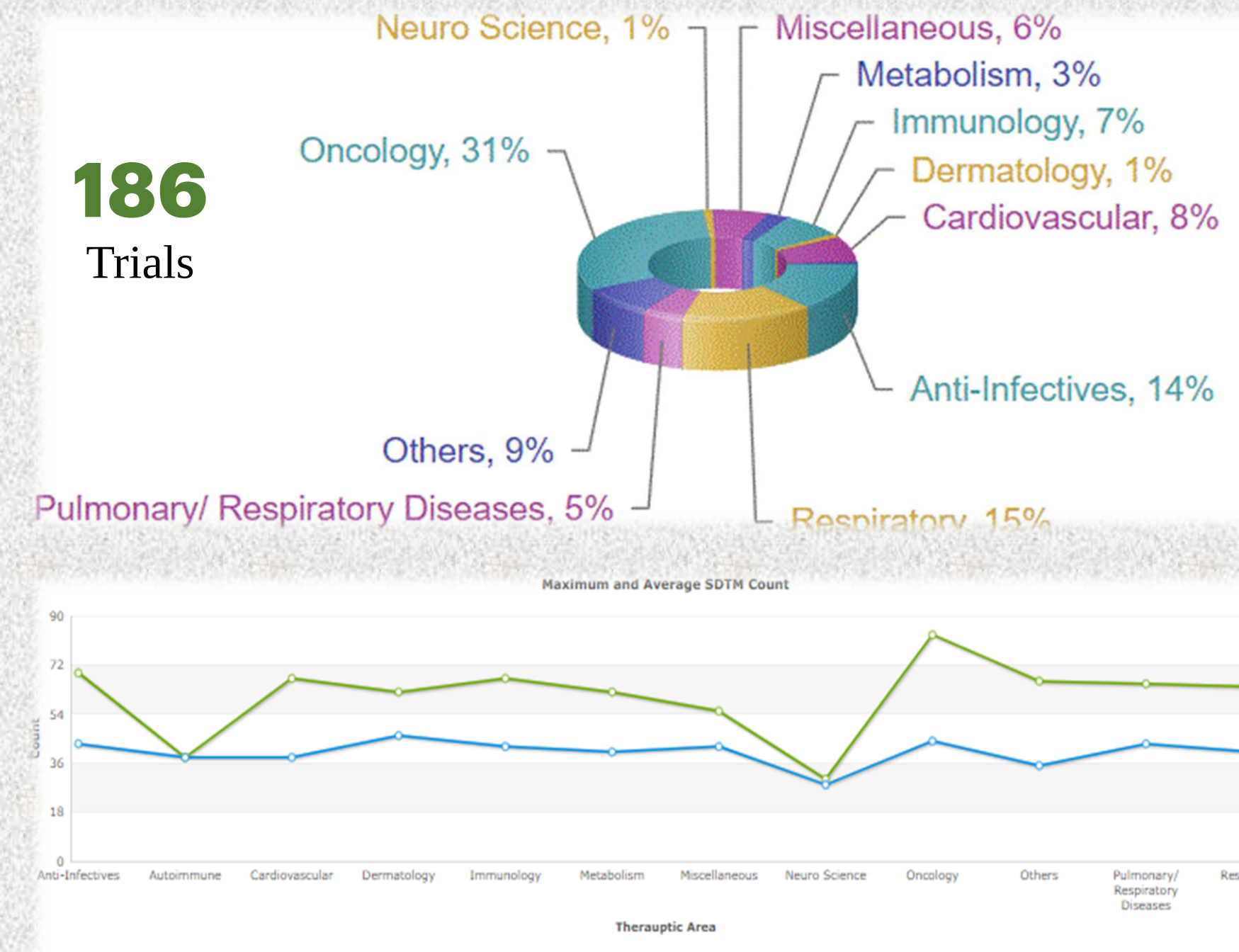
OUTCOMES

Since 2013, the tool has processed
11,300
Source Data

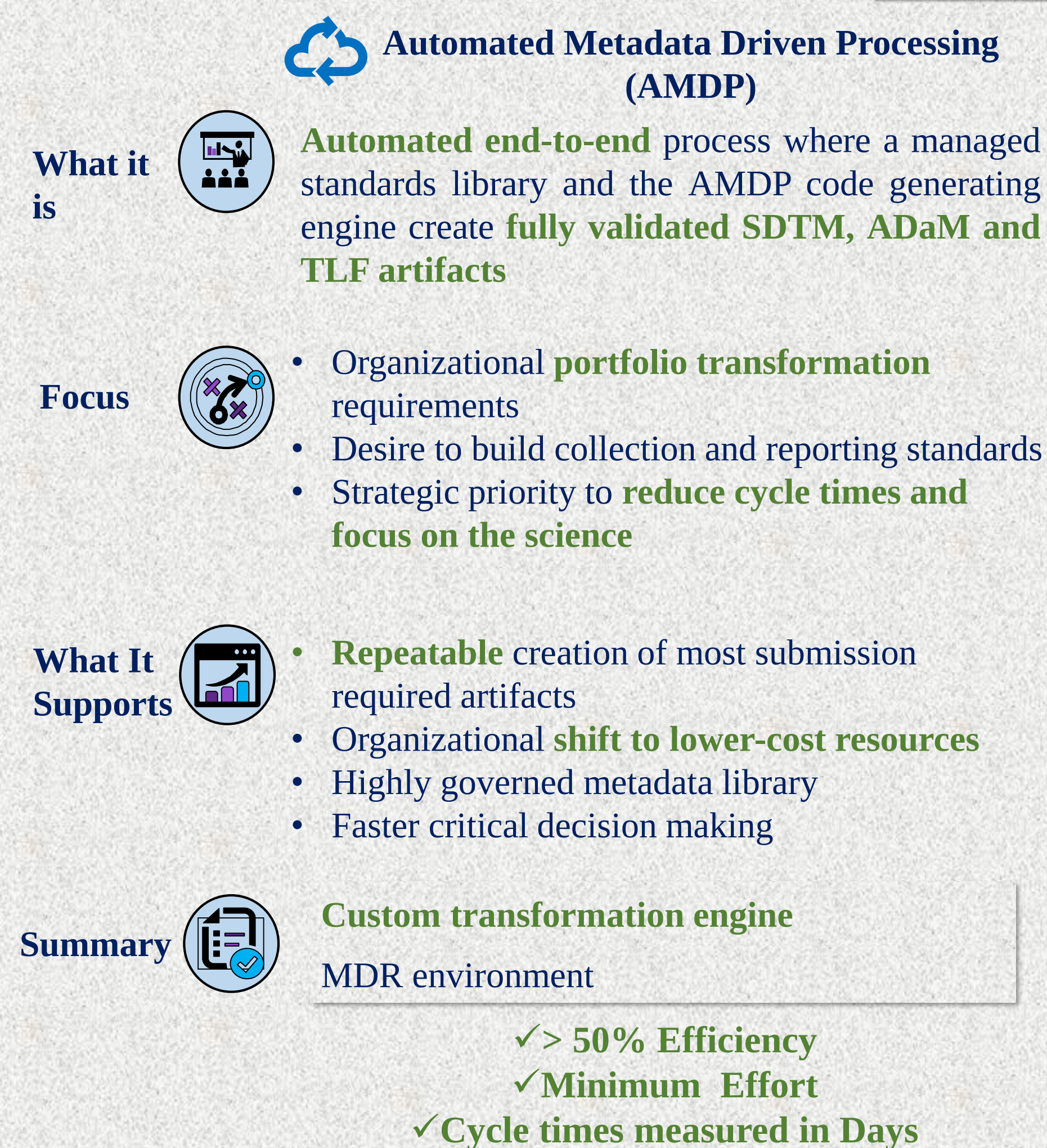
Our most mature SDTM mapping automated toolset, it has more than
22,000
Active Global Mapping Algorithms

Since 2013, the tool has produced
7741
Compliant SDTM Domains

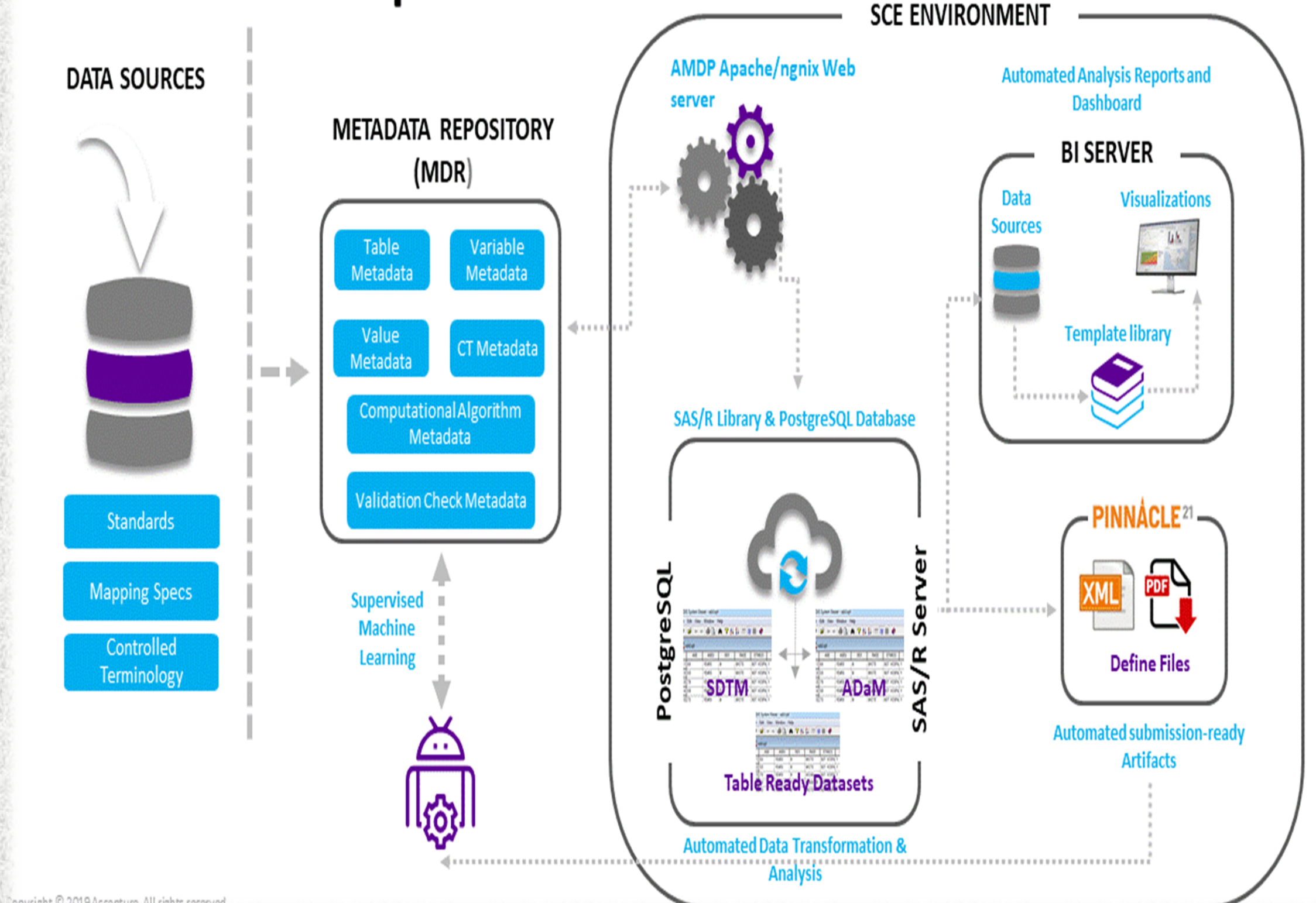
SDTM Conversion	Yr. 2013		Yr. 2019	
	Early Phase	Late Phase	Early Phase	Late Phase
Study Cycle (in Days)				
Initial	18	23	10	12
LSLV	14	14	10	10
Data Base Release	7	7	5	5
Data Base Lock	5	5	3	3



NEXT WAVE – A GIANT LEAP



ROBOTIC PROCESS AUTOMATION | AMDP



CONCLUSIONS

It costs approx. \$2.9bn. for Pharma and Biotech industry to successfully develop a new drug and bring it to the market for its commercial use. The current research data suggests that ROI is declining and the R&D budget is reaching to the sky. The next wave, near wave and horizon of the clinical trials, can only be achieved if the Pharmaceutical industry leaders recognize the importance and advantages of pivoting to this exciting future. The accessibility of technology will have a huge impact on everyone involved in the clinical trial process, including the data management and operations group. Data complexity and data volumes are challenging today's business models and driving up the cost of research and development. The AI, ML-driven solutions provide a powerful mechanism that can improve business performance and strengthen the decision-making process. It is critical for the industry to carefully determine the types of tasks, strengths, and limitations of each in order to go through technology upgrades. The foundation pseudo-automation solution offers sponsors to expedite CDISC SDTM submission compliant deliverables with optimum quality and consistency using their data standards. This foundation now has become the incentive to understand the unknowns of the current process and bring further automation with integrating with other novel technologies to offer a better, more efficient product.

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