Clinical Pharmacometrics: modeling and simulation
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What is Pharmacometrics?

"Pharmacometrics is … the science that quantifies drug, disease and trial information to aid efficient drug development and/or regulatory decisions…The single-most important strength of such analyses is its ability to integrate knowledge across the development program and compounds, and biology." FDA

Typical clinical questions answered through modeling and simulation

Which dosing regimen is best for newborns?

Does hepatic impairment change patient reponse to treatment?

How does our asset compare to comptitors?

What effect do diet/demographics have on the patient outcome?

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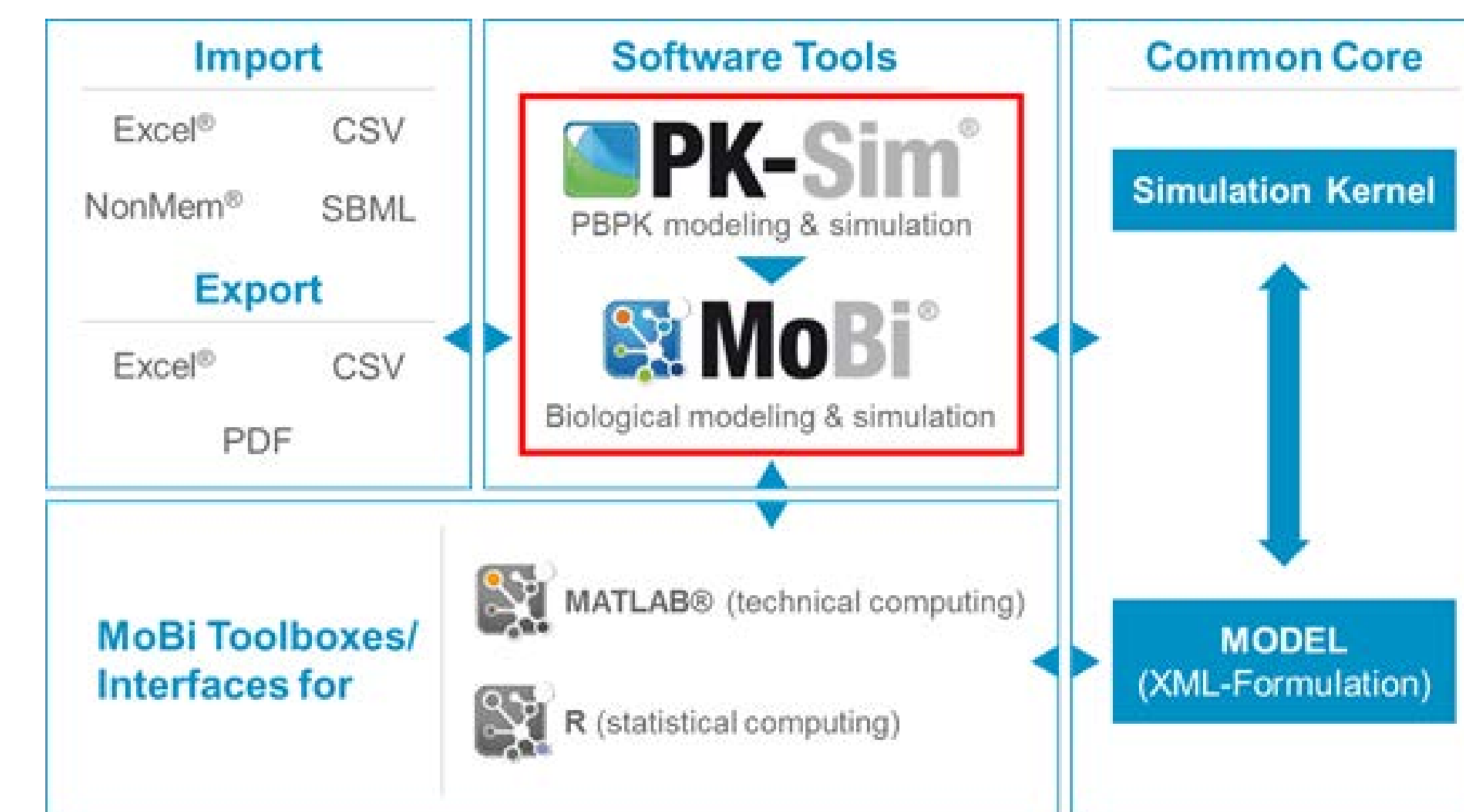
Products defined, now maintained by DevOps team
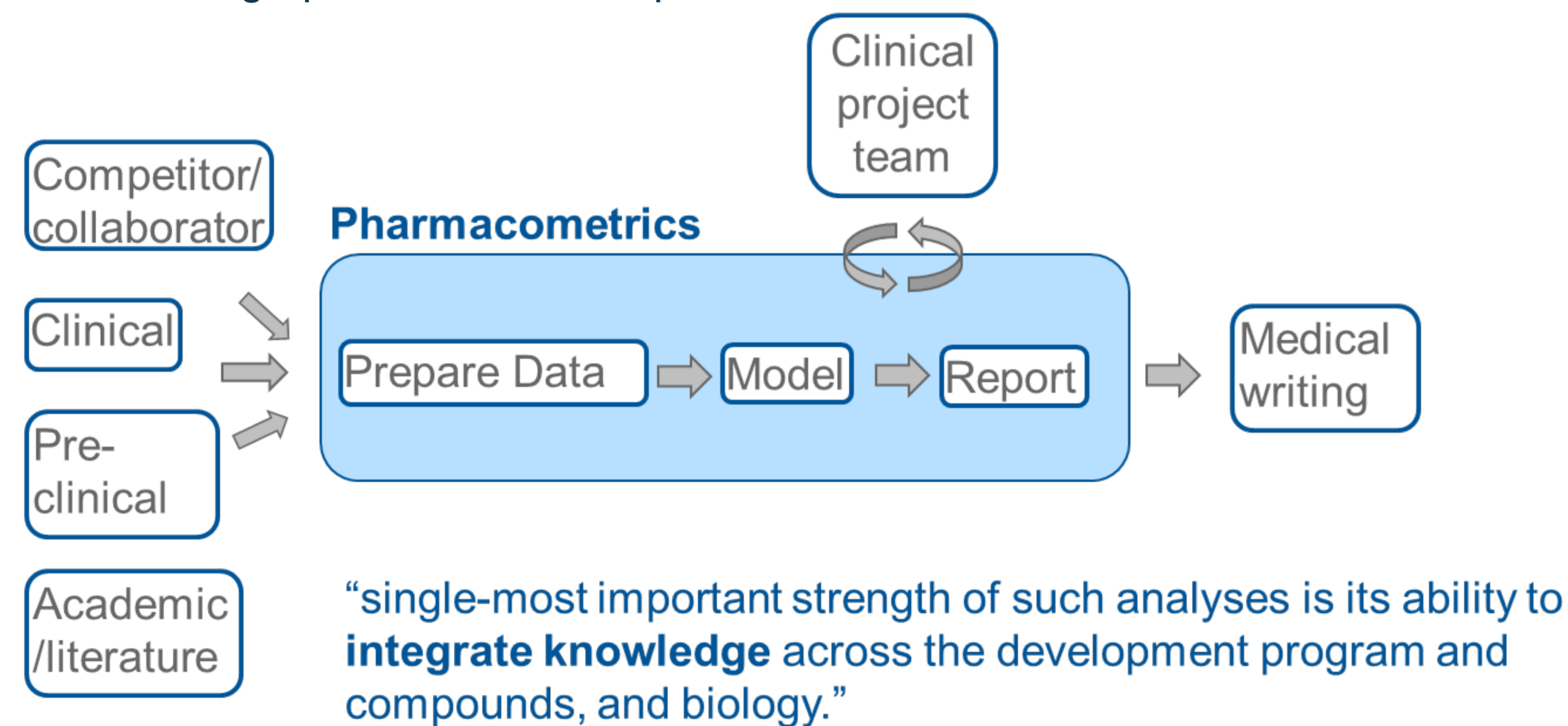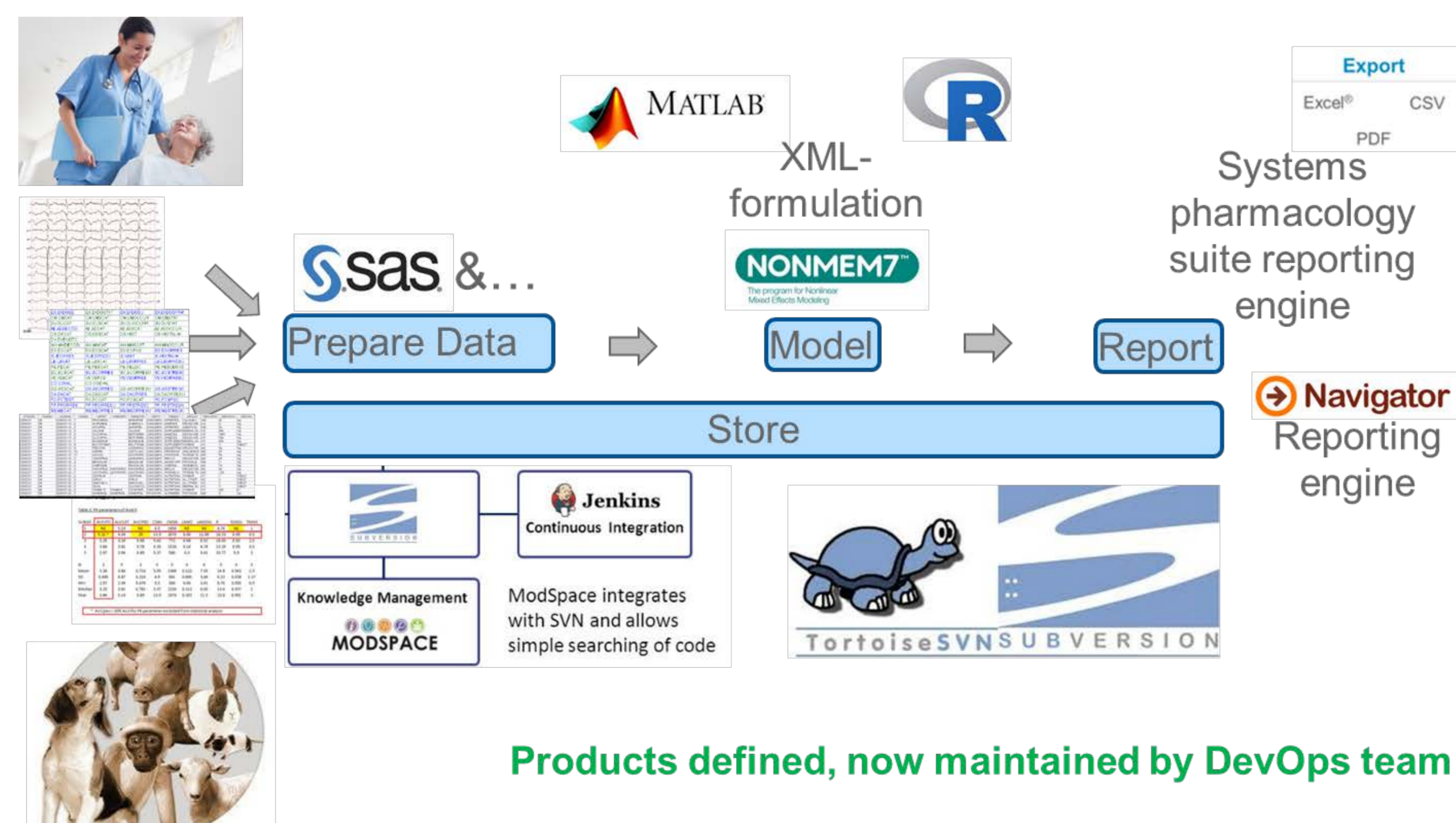
Categories of models covered by pharmacometrics

Drug models: dose - exposure – response (explaining variability in patient populations)

Disease models: biomarkers – clinical outcomes

Clinical trial models: inclusion/exclusion, patient-discontinuation & adherence.

ⓘ The systems pharmacology suite developed by Bayer Technology Systems, now open source

Outlook 2018/19

Validated R: R is an open source statistical programming language, validated R environment and validR library established: currently 25 users Current state: extending to biostatistics, next step biologics. End goal: all of Bayer.

Elastic cloud: First export of Bayer restricted patient data in an external cloud. Validated modeling environments established using amazon web services for: nonmem, R and matlab.

Intelligent timing In house development of machine-learning based approach to prepare diverse datasets for modeling.

SmartQC: Use of natural language processing and other technologies to automatically quality control submission documents. In contact with regulatory affairs eSubmissions.

DWOT: Data, workflows, ontologies and tools: ensuring full traceability of analysis.