

The Open SCE: A Call to Action One Year Later

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The Open SCE Initiative



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Lasting, evolving, community-driven, open-source SCE framework



Challenges:

Service & Software
Vendor Heavy

Lack of Focus

Inconsistent Engagement

We interviewed key stakeholders

- *How do you define an SCE within your organization?*
- *What is the current state of your company's SCE solution(s)?*
- *What modernization efforts are you currently undertaking for your SCE?*
- *What gaps or challenges are you encountering with your SCE solutions?*
- *Where do you see opportunities for open-source solutions to address these gaps?*



We found variations in idea of scope

1

SCE for primary use
(ADaM and TFL Creation)

Manage clinical trial data, transforming it into ADaM and creating TFLs for submission

Uses cloud solutions with orchestration to automate workflows and ensure compliance

2

Modelling and simulation
for pharmacokinetics

Support advanced modeling, particularly for pharmacokinetics, ensuring efficient analysis

Handles complex datasets and integrates with modeling and simulation tools

3

SCE for secondary use

Repurpose trial data for exploratory research and real-world evidence

Focuses on metadata-driven reuse, Requires agility and use of AI for insight generation

We found common struggles with SCE solutions



Clinical data management

Manual task orchestration causes inefficiencies, driving a shift toward automation and AI for better management and planning



Code repository/Git

Git's complexity challenges non-developers, especially statistical programmers, prompting calls for simpler, more user-friendly interfaces



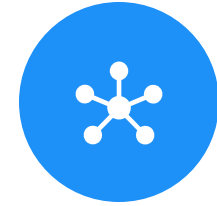
QC management

Double programming for quality control is viewed as outdated and labor-intensive



Validation

Interest is growing in automating validation to boost efficiency and reduce team workload



Barriers to open-source adoption

Challenges in sustainability and integration

Opportunities for AI Enablement



Automating QC processes

AI can automate the validation of code, ensuring unbiased and rigorous quality control with reduced errors



AI-generated code

AI can generate initial drafts of code based on statistical analysis plans, streamlining coding and speeding up production



AI in data cataloging

AI can assist in efficiently navigating and retrieving data from large datasets, simplifying the process of data cataloging



Synthetic data generation

AI can create synthetic datasets for pre-testing, allowing early testing and improving reliability before real data is available



Enhancing orchestration

AI can optimize task allocation by predicting workloads and automating routine processes, leading to more efficient workflows



Real-time data access and processing

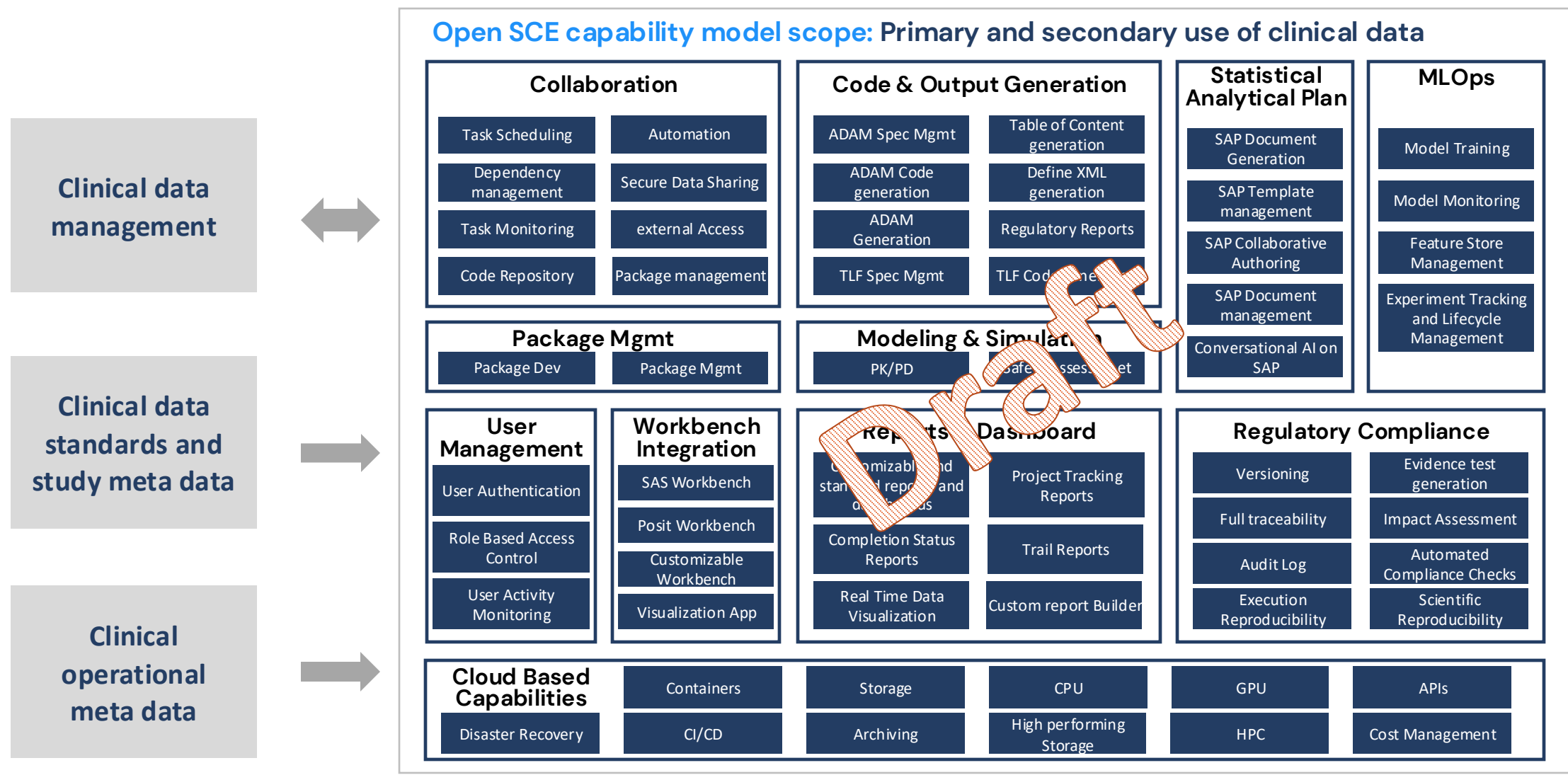
AI can enhance real-time data access by automatically linking metadata for faster data retrieval and analysis



AI-driven QC and development

In the long-term, AI agents could independently verify code and conduct QC, minimizing the need for human intervention

Capabilities Model: Managing Commonalities and Differences



Restructure Around New Focus

Key Findings

Consensus:

- Integrated and automated orchestration layer
- Robust code management based on git
- Improved QC processes

Differences:

- Specific implementation plans
- Overall scope of SCE solutions

New Open SCE projects

1

Git in statistical programming

Create a best practice guide for using Git in statistical programming, then develop a Git abstraction tool for simplified code management

2

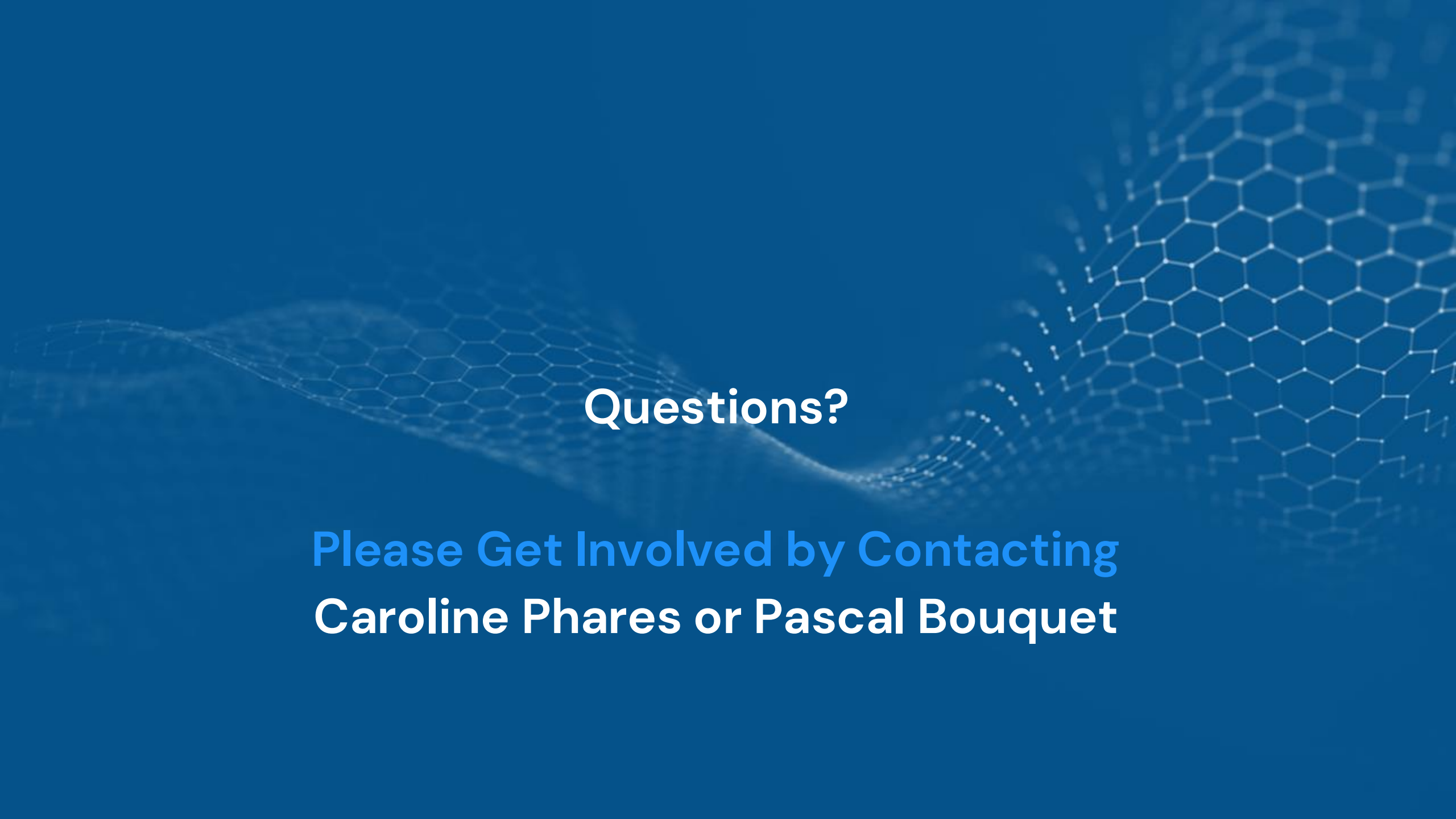
SCE capabilities model

Refine the capabilities model to define SCE components, then develop Gherkin scripts for test-driven requirements

3

QC management

Harmonize QC best practices, then explore AI-driven solutions to streamline the process



Questions?

**Please Get Involved by Contacting
Caroline Phares or Pascal Bouquet**