



From Pilot to Production: The Generic Safety App as a Validated Platform for Clinical Trial Safety Review

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Agenda

- Background and Challenge
- From Pilot to Validated Platform
- Adoption and Real-World Impact
- Looking Ahead: Best Practices & Expansion
- Q&A



Background and Challenge

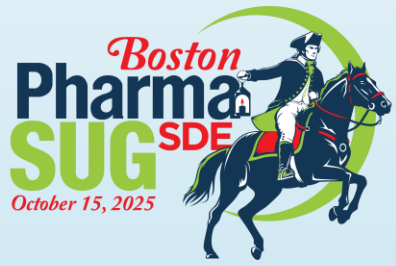
Static data displays, overwhelming review burden, slow decisions

Data monitoring committees (DMCs) in a nutshell

DMC is a group of experts that reviews the ongoing conduct of a clinical trial and the emerging data to ensure continuing patient safety as well as the validity and scientific merit of the trial

- ▶ DMC is responsible for recommending continuation, modification or termination of an ongoing study
- ▶ DMC operates independently of the clinical trial team
- ▶ DMC receives (long) report about emerging data
 - Trial progress, patient disposition, medical history, con meds, efficacy, safety
 - Report provided by independent reporting group/statistician





Challenges:

- ▶ Hundreds of pages of static TFL
- ▶ Scattered source of information (ad hoc requests)
- ▶ Tight timeline, overwhelming review burden

We want:

- ▶ Interactive safety data displays with drill-down capabilities
- ▶ Generalizable, scalable, intuitive solution: no additional burden to trial team, CRO, or DMC members



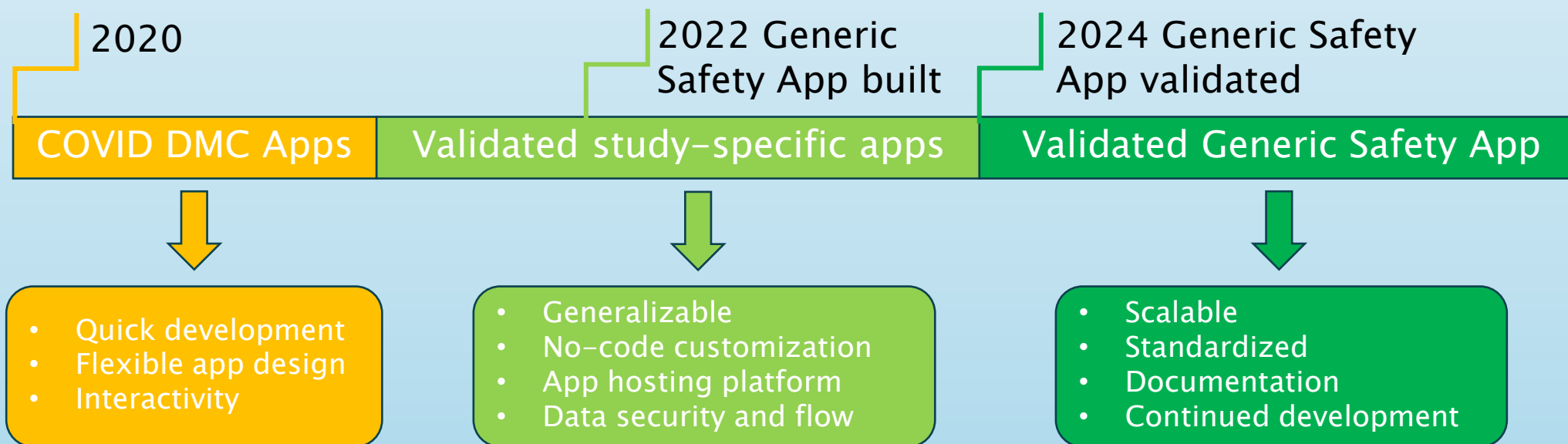
**Generic
Safety App**



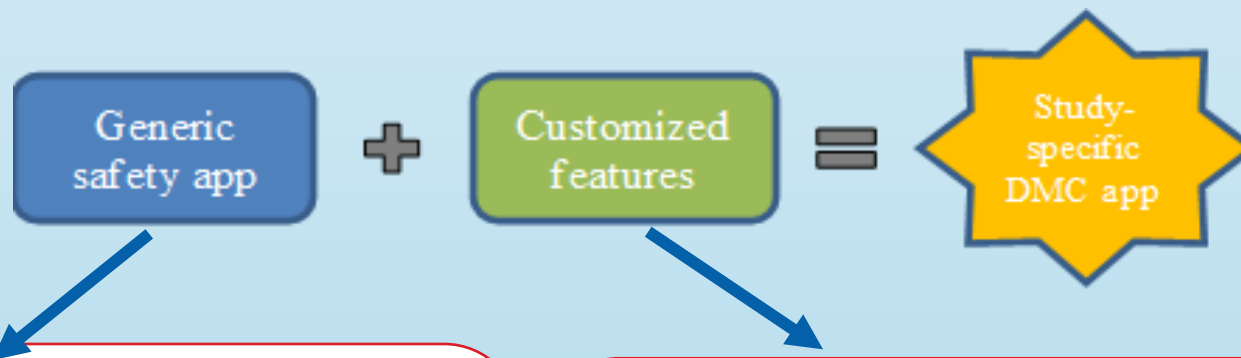
From Pilot to Validated Platform

Standardization, customizability, documentation, compliance

Timeline:



Generalizable & customizable:



Code for analysis and reactivity (R, JS React)

- No project-specific information or hard-coded variable names and parameters
- Managed by app dev team and **validated/up-versioned periodically**

Using a JSON configuration file

- Standardized format to collect project-specific information
- No-code solution to develop project-specific apps
- Remove validation requirement for project-specific apps

Standardized & documentation:

- Part of enterprise-wide DMC process improvement initiative
- Validated instances deployed as placeholders
- Standard process to load data and config file for specific studies
- External user onboarding process simplified

Standard Process

- DMC Charter Template
- Generic Safety User Manual
- How to Customize Generic Safety App for Your Clinical Project
- How to Deploy Generic Safety App
- Service Request Templates for Data and Config Load and User Access
- Trainings and workshops

Comprehensive documentation



Adoption and Real-World Impact

Scaling up, driving insights

Impact



Supported 30+ DMC meetings, of which 10+ used validated generic instances



Decreased app deploy time from 8+ weeks to ~2 weeks



Scalable across different Disease Units



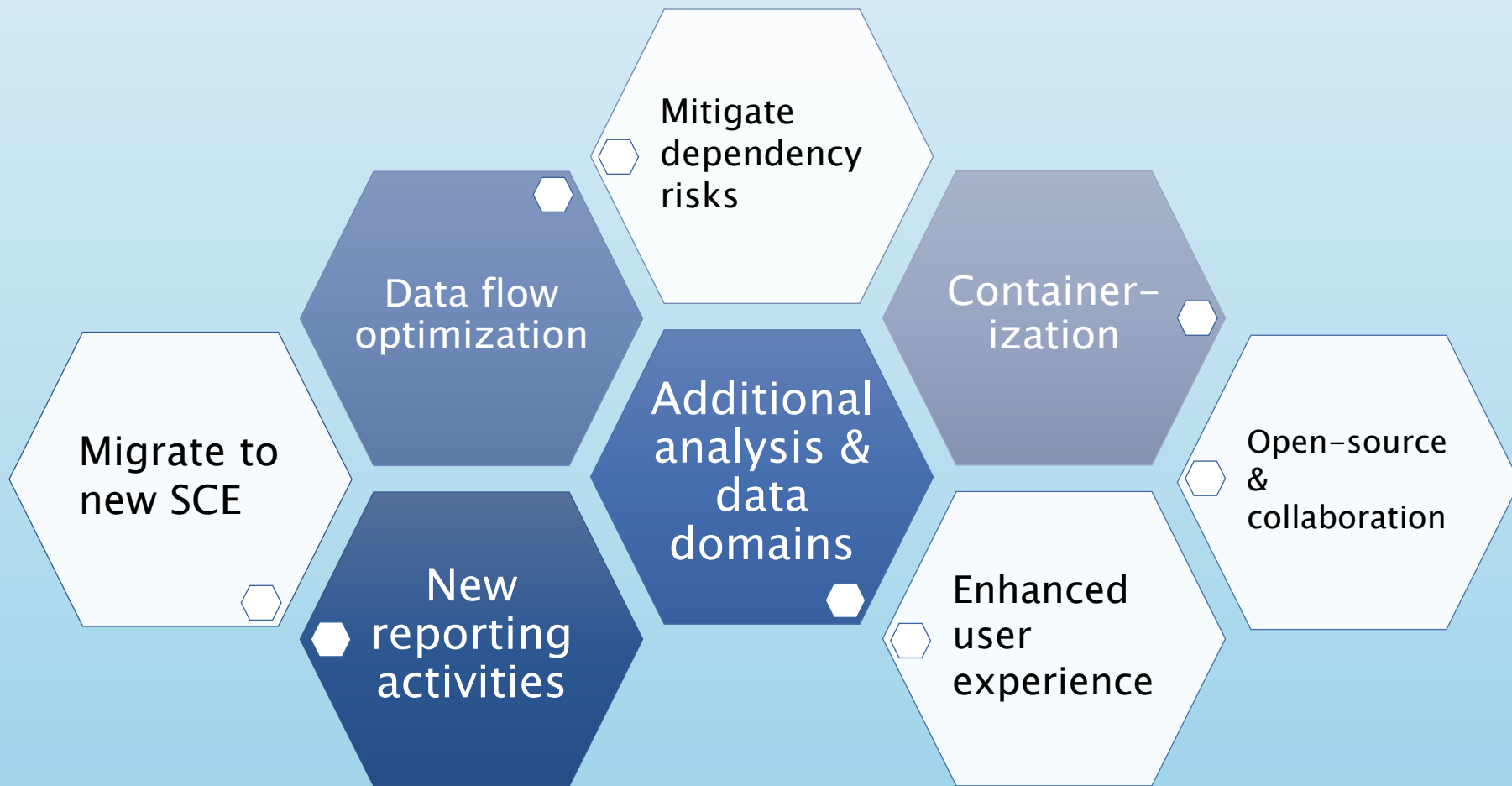
GxP compliant and well documented



Looking Ahead: Best Practices & Expansion

Process optimization, continued development, and new use cases

Looking ahead:





Acknowledgement

App dev team:

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Thanks! Questions?



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