How Commercial Software Companies Can Encourage Open Source Development

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Presentation Outline

- Propriety and Open Source Software (OSS)
- 'Proprietary Sandwich'
- Examples of OSS contributions via proprietary development
- Current and potential applications in clinical development

About Medidata Solutions

We are a global technology company that provides a SaaS platform for clinical trials.

Core components of the platform include EDC (Rave), IWR/ IRT (Balance), CTMS, Analytics (Insights), Trial Planning Solutions, and Protocol Design

Estimate that close to 50% of all the data on pharma clinical studies move through our platform

‘Proprietary Sandwich’

Open Source Apps	• API’s • Standards
Proprietary Platform	• EDC (Rave) • IWR (Balance) • Analytics (Insights)
Open Source Stack	• Linux • Ruby on Rails

1. Release OSS to the Community

- Medidata views it as our ‘corporate debt’ to give back open source software
- Contribute open source code back to community
- Program conceived by software engineers and legal in late 2012
- Formal program rolled out in Q1 2013
- Policy and Process to provide path

2. Open Platform VIA API's and Standards

- Application Programming Interface (API's)
  - Vehicle by which other software or code can connect to the platform
  - Common among many commercial software solutions

- Standards encourage collaborative development
  - Makes it easier to for disparate developers to build apps that work collectively (ex CDISC)

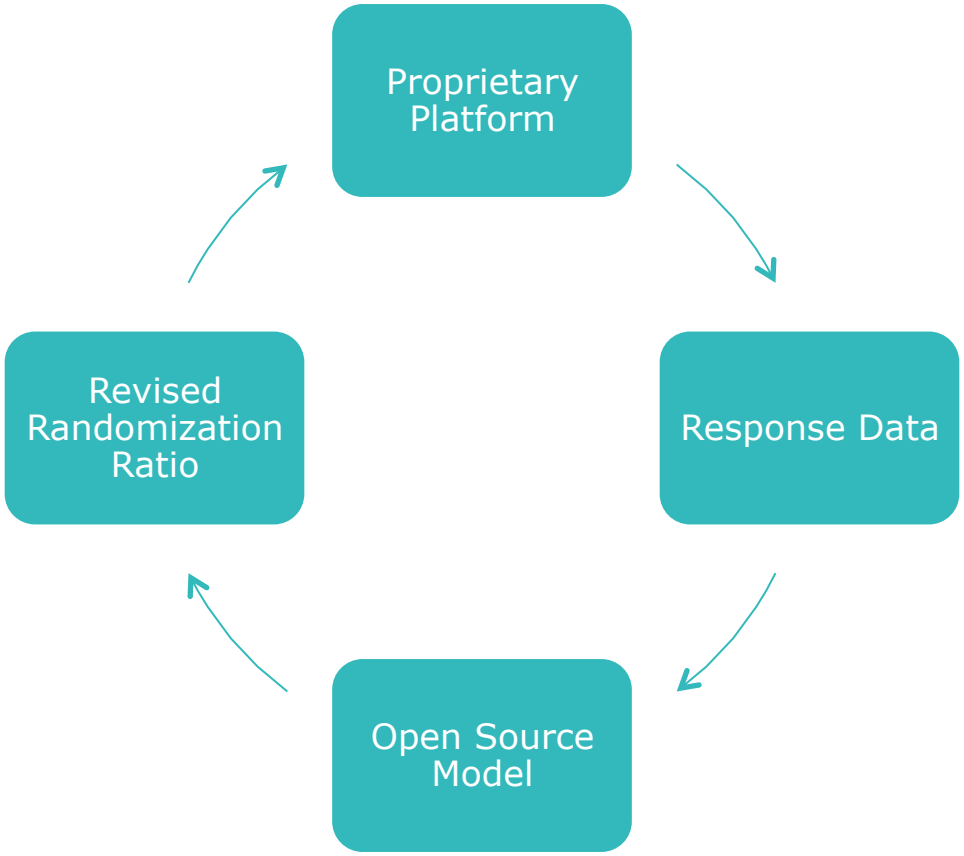
MDSO Example: Developer Central

- An online community to support sponsors in their efforts to integrate various clinical trial solutions with the Medidata platform
- Intended to foster innovation and is a free service available to sponsors and others in clinical development
- Unfortunately, used mostly for point to point integration – not up to it's full potential

Developer Challenge

- Open the platform to the broader developer community
- Encourage open source development
- Want to tap into the living dynamic to see if we can learn from it and our customers can benefit from it
- Potential to extend platform to the benefit of our customers (clinical research Apps)
- Apps could be from commercial or academic/non-profit organizations, and be available at no cost (preferably no cost)
- First challenge: Patient engagement

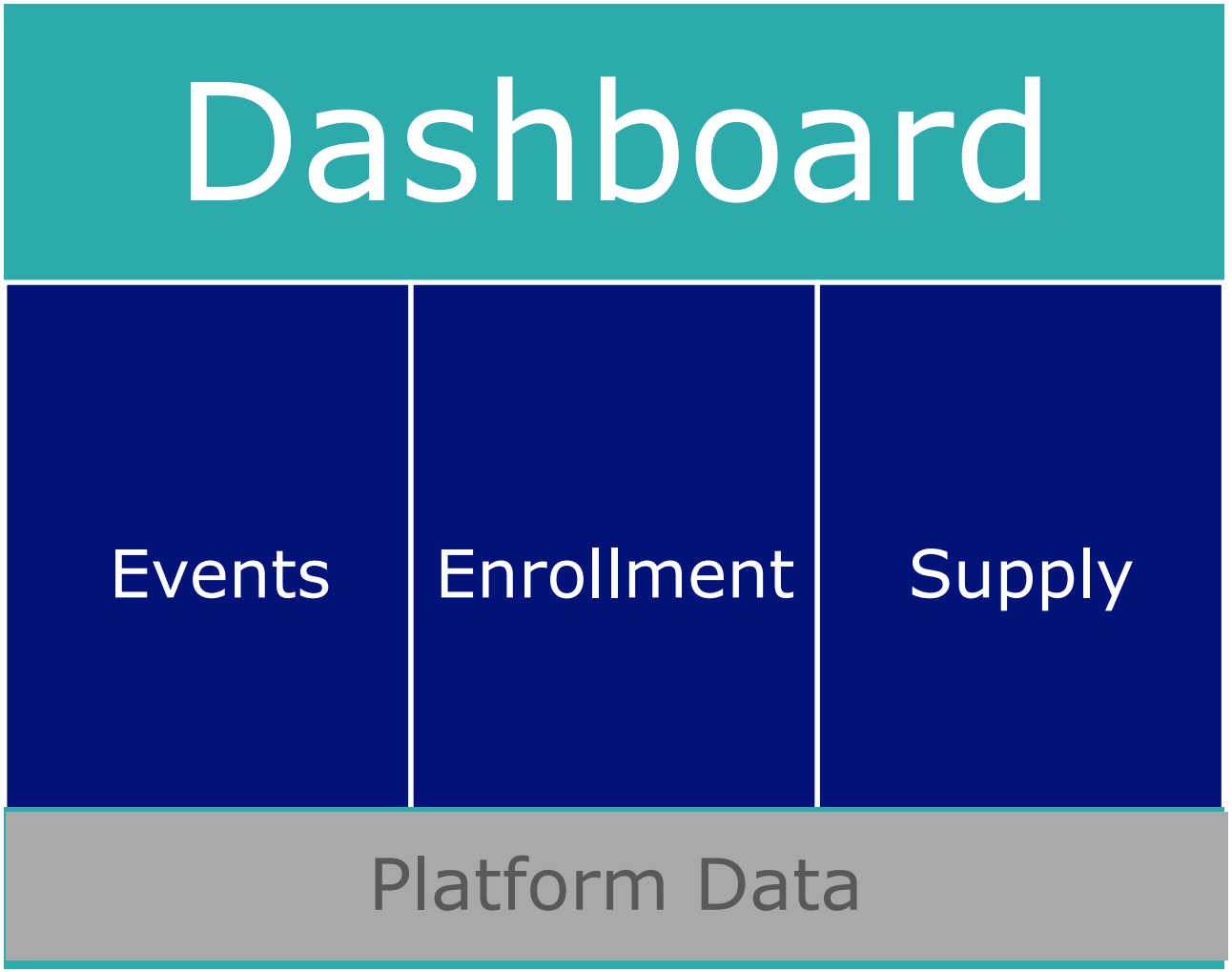
Response Adaptive Trial



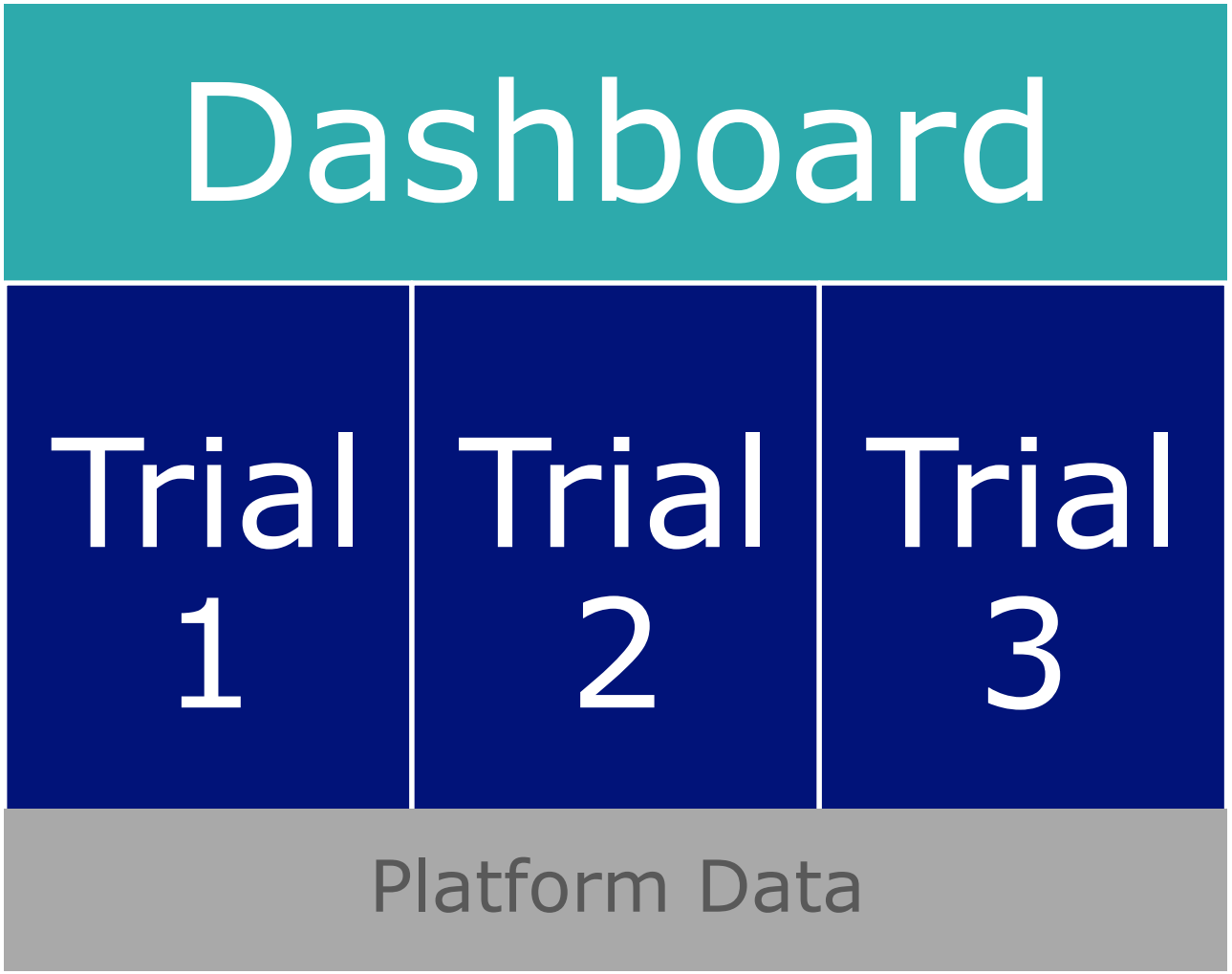
On-study event/enrollment modeling

- **Early in study - Identify problems & Refine Planning**
  - Are the protocol assumptions accurate?
  - When to stop enrollment?
  - Expected # patients (enrolled, randomized, etc)?
- **Mid study - Evaluate Fixes & Monitor emerging issues**
  - When to stop randomizing patients?
  - Are the revised assumptions accurate?
  - Were changes effective?
  - Do we need to re-evaluate our drug supply plans?
- **Late in study - Plan for Closeout & Database lock**
  - When will the last Relapse occur?
  - How many patients will be active in various phases?

Predictive Trial Analytics



Program Analytics



Summary

- Even companies that develop software with a proprietary model can contribute free and open source software

- Commercial software companies and the user community can benefit by opening their solutions via API's

- Companies should facilitate and enable 3rd party developers

There is significant untapped potential to improve clinical development by extending the capabilities of existing commercial platforms

Balance Professional Services

Implementation Statement: Balance is a configurable RTSM solution that makes it possible for studies to be setup by Medidata, partners, or sponsors themselves with minimal training.

- Study by Study
  - Medidata or Partner Build
- Enterprise Adoption - Knowledge Transfer
  - Enablement workshops
  - Mentoring
- 24/7 help desk
- Many enabled partners (and growing)

Thank You

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