Who Is Intersect ENT

A medical device company dedicated to advance the treatment of ear, nose and throat (ENT) conditions through evidence-based innovation, and solutions for physicians to overcome clinical challenges and improve the quality of life for patients.
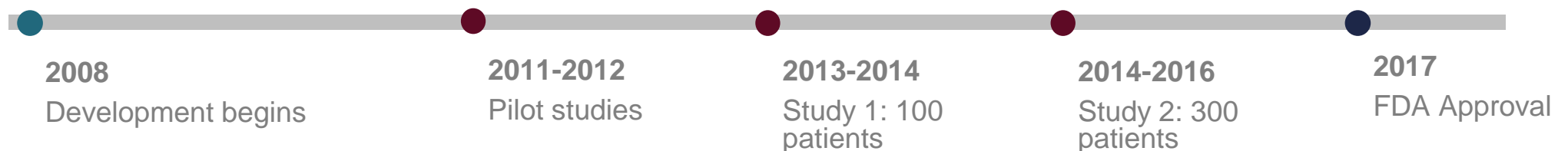
Who Is Intersect ENT

Founded in 2003 | 325+ employees today | Approx. 2 studies per year

PROPEL (device)

2006
Development begins

2009-2010
Pivotal study
105 patients

2011
FDA Approval

2014-2016
PROPEL Mini & Contour
160 patients

Sinuva (drug)

2008
Development begins

2011-2012
Pilot studies

2013-2014
Study 1: 100
patients

2014-2016
Study 2: 300
patients

2017
FDA Approval

As a Medical Device Company

What we face	What we need
• Team members wear multiple hats • Multiple protocol cycles • Compressed timelines	• Greater efficiency • Quick, easy EDC builds • Intuitive solutions

Challenges

intersect® ENT

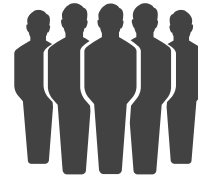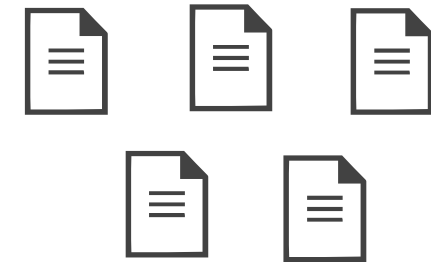| EDC	CTMS	eTMF	Payments

Compressed study builds

Manual processes

Payments

Two Main Vendor Approaches

One Vendor

- Promise of integrated applications
- ROI prioritized over innovation
- No consistency
- Increased training

Point Solutions

- Sponsor chooses best fit of applications
- Not forced into one vendor's solutions
- Integration is an additional cost and effort
- Doesn't always work as promised

A New Approach: Unification

intersect® ENT

- ✓ Applications on unified platform
- ✓ Same look and feel across all products
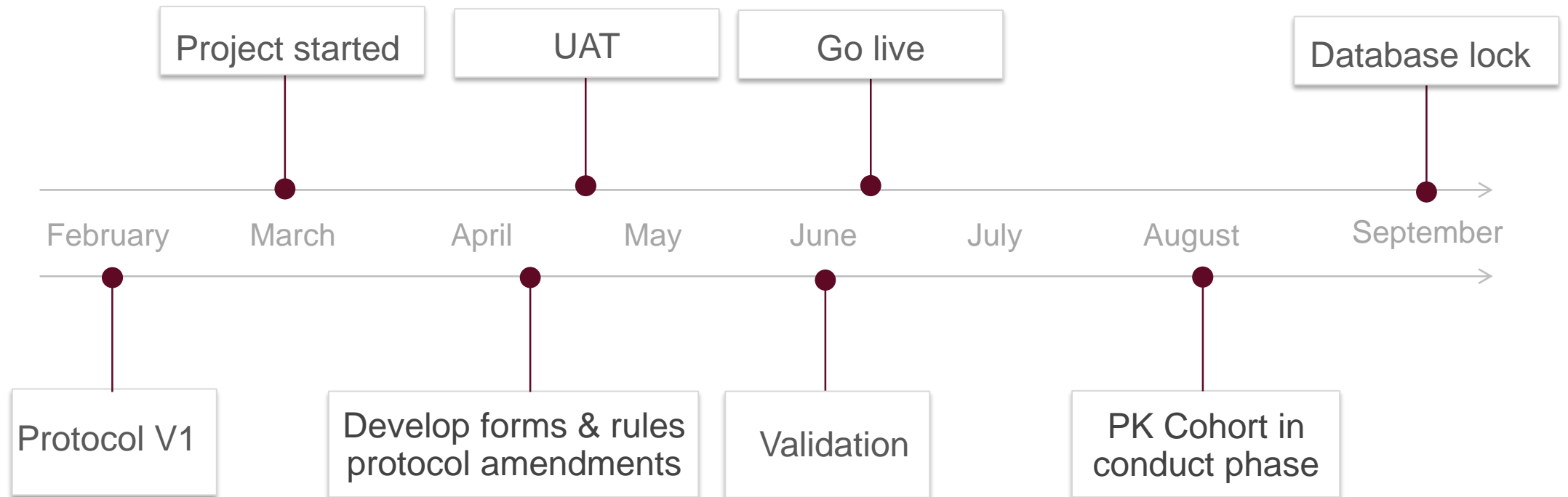- ✓ Constant innovation

Why Veeva

- **Started with Vault PromoMats**

- **Opportunity to automate clinical operations**

- **Best of both approaches**

- **Low-risk decision to try Vault EDC**

Implementing Vault EDC

Device study, 2 cohorts

Project started	UAT	Go live		Database lock

February — March — April — May — June — July — August — September

Protocol V1

Develop forms & rules protocol amendments

Validation

PK Cohort in conduct phase

What's Worked

- **Early adopter – influence product development**
- **Common interface across all Vaults**
- **Constant innovation**
- **System works as expected**
- **Positive site feedback/experience**

Lessons Learned

- **Setting internal expectations about Early Adopter**

- **Missing features we've become used to**

  - **Form statuses**

  - **Ad hoc reports**

  - **Exports on demand**

- **"Hamster Wheel of Change"**

Future Vision

- Improve unification between EDC and CTMS
- Site payments

- Add medical device requirements
- Device accountability
- Imaging

- Improve site and user administration
- Improve eLearning administration

In Summary

- **Desire to move away from stand-alone applications**

- **Successfully implementing Veeva's suite**

- **Feel positive about the future of Veeva unification**

Thank You