



Best Practices for
Vault eTMF Implementations

Melissa Aron, R&D Practice Manager

Safe Harbor

The following is intended to outline Veeva's general product direction. It is intended for informational purposes only and does not form part of any contract. It is not a commitment to deliver any specific functionality and it should not be relied upon in making purchasing decisions. Features and functions described in this document will be released commercially only when and if they become available. The development, release, and timing of the features or functionality of Veeva's products remains at the sole discretion of Veeva.



Today's Session

- **Identify your starting point and goals**
- **Examine effective resource allocations and timelines**
- **Tips to stage deployment of features**
- **Considerations on how to improve user adoption**



Where Are You on the Continuum?

Central Processing Models

Integrated Models

**Traditional
100% Paper**

Paper during
execution &
in archival



Where Are You on the Continuum?

Central Processing Models

Integrated Models

Traditional
100% Paper

Paper during
conduct,
eArchive

Paper during
execution &
in archival

Paper during
execution, scan
to electronic
after study close



Where Are You on the Continuum?

Central Processing Models

Integrated Models

**Traditional
100% Paper**

**Paper during
conduct,
eArchive**

**Active
Electronic
Repository**

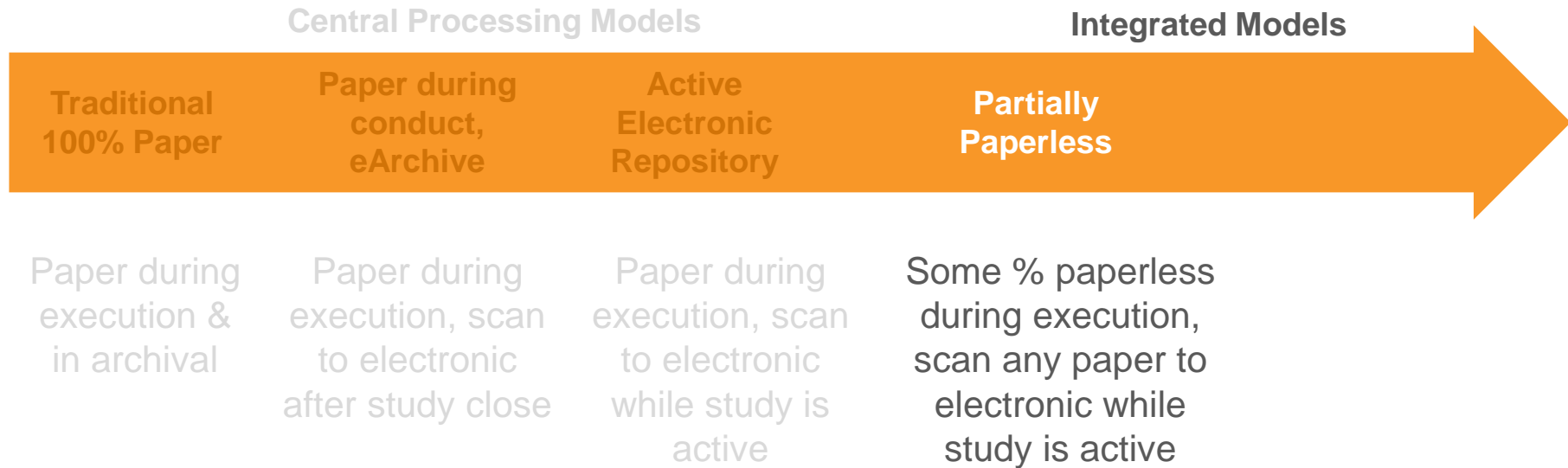
Paper during
execution &
in archival

Paper during
execution, scan
to electronic
after study close

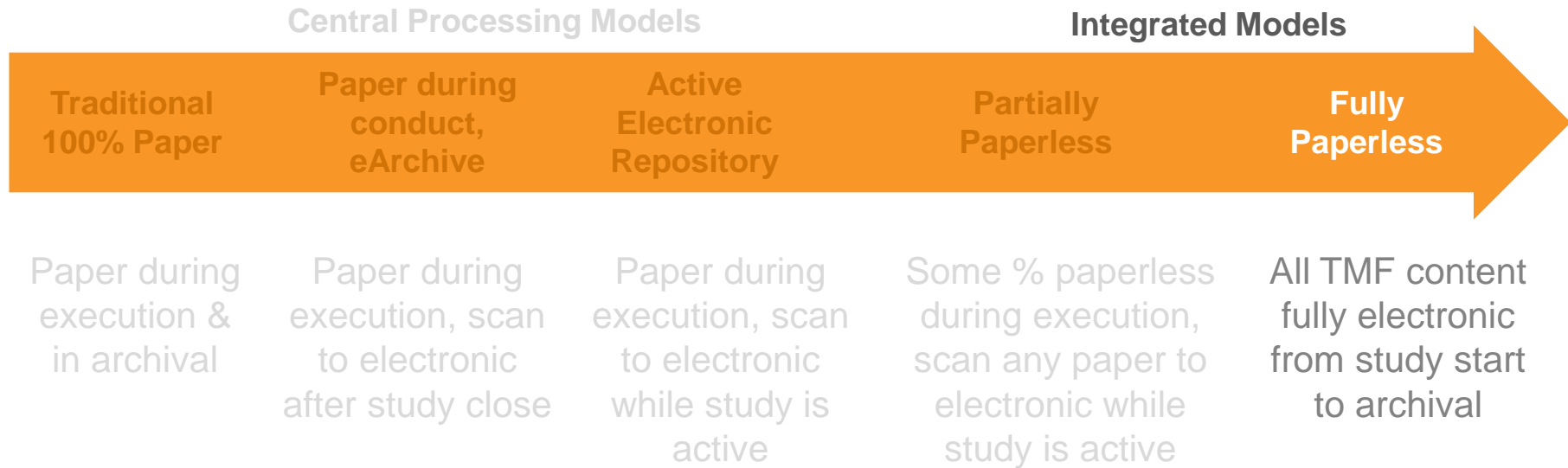
Paper during
execution, scan
to electronic
while study is
active



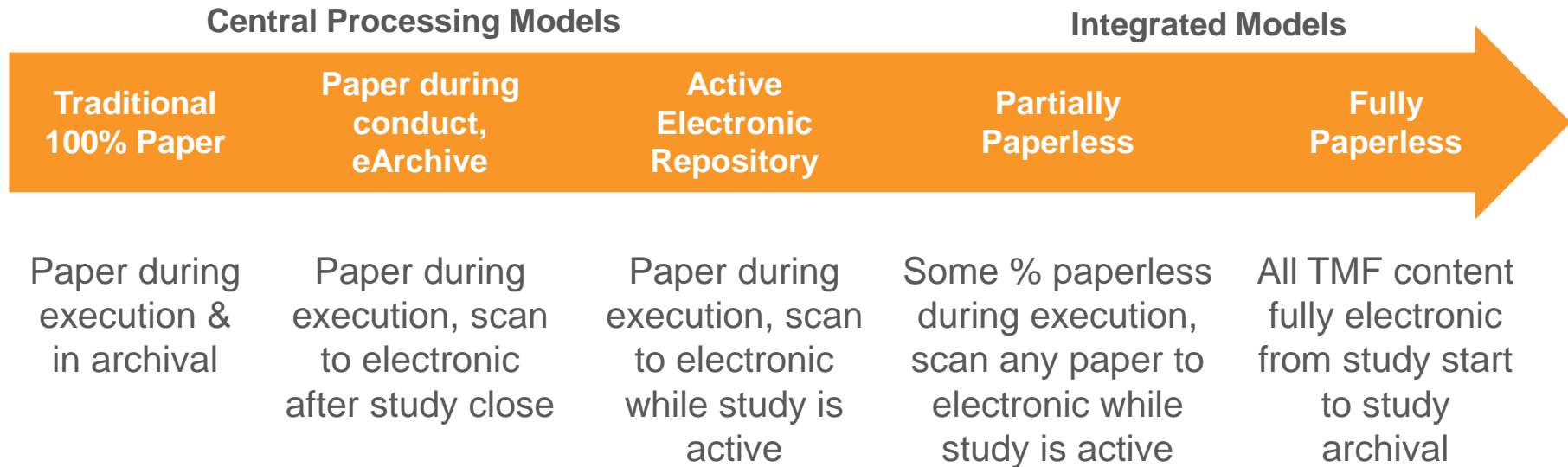
Where Are You on the Continuum?



Where Are You on the Continuum?



Where Are You on the Continuum?



Set Project Goals: Short Term & Long Term

- **Who will use your system?**

- Your own clinical staff
- External partners like a CRO (or for CROs, the sponsor)
- Investigator sites

- **How will you use the system?**

- As an archive
- As a collection tool
- To draft, review and approve some information and collect other things
- To share information with sites
- To track study completeness
- To monitor metrics
- As an ISF



Project Planning

■ Factors for timeline

- Organizational size/volume of studies
- The team — availability and background
- Status of processes, document type model definition

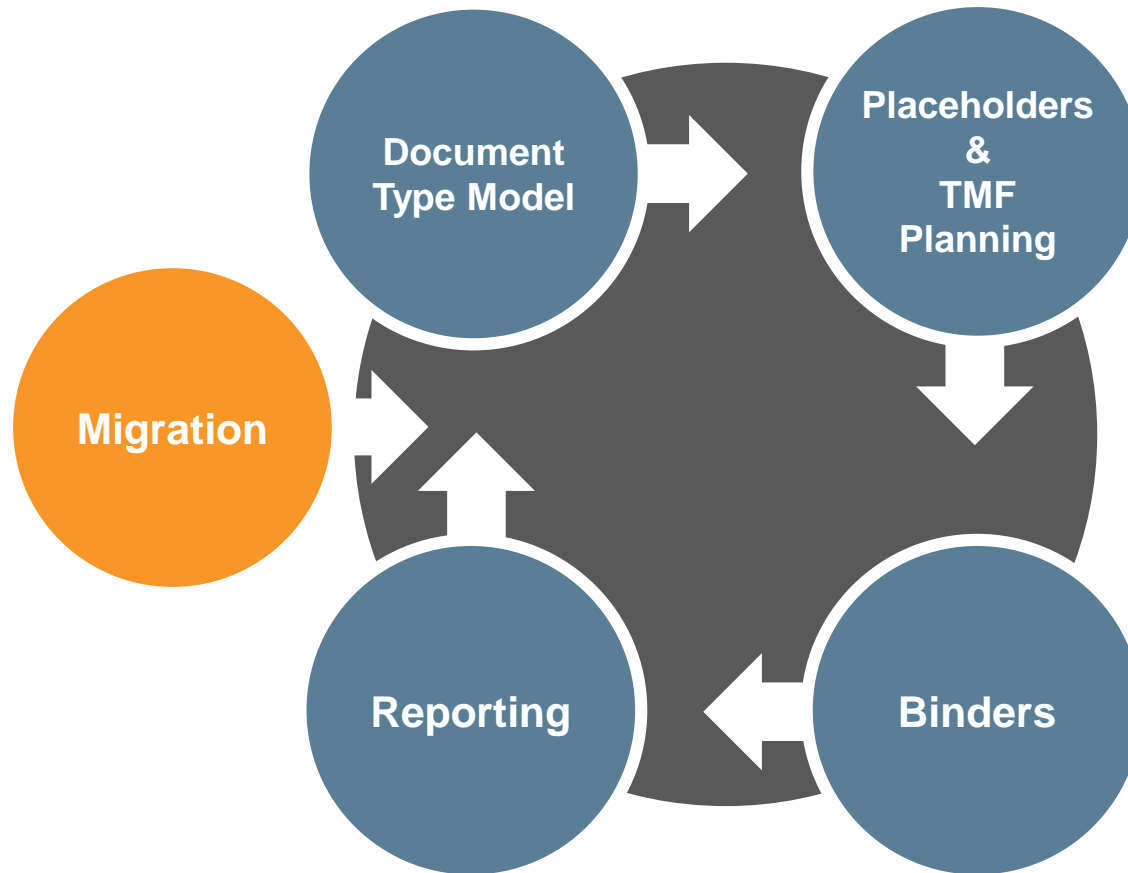
■ Choosing the right people

- Which Roles?
- Engaged
- Enthusiastic
- Innovative
- Available

■ Promote and demand participation



Impacts of Your Document Type Model



“Where do I need to file this document?”

- Many post-go-live support questions are due to confusion regarding the new object model
- Proactively plan for document type training



Building out the Workflow and Lifecycle

Stay Flexible

**Expect different trials, regions,
CROs to work differently**

Don't overcomplicate with "special rules"

Open Security where possible

"The system doesn't work.
I can't find what I'm looking for."

Stay with the Basics

**90% of typical scenarios addressed
by OOTB lifecycles and workflows**

**Go for low hanging fruit —
add extra processes later**



The way to get started
is to quit talking and
begin doing.

Walt Disney

Controlled and Calculated Ramp-up

Many more...

Relationships
between docs

Document
type specific
processes

Integrations

Format specific
processes

Site Access

Planning &
Tracking

Lock, Closeout
& Archival

Metrics &
Reporting

Unblinded
Information

Basic Filing &
Classification

Approval &
eSign

User
Onboarding

Audits &
Inspections

Study/Country/
Site Initiation

Document Type Model Definition



Improving User Adoption

- **Change management from selection onwards**
- **Focused application training**
- **Separate object model and process training, role based**
- **Take advantage of Vault's OOTB help materials**
 - Focus your efforts on process related materials
- **Consider your external users when evaluating where to host training materials**
- **Open, regular forums for Q&A**



Deployment Plan



Support Structure

- **Who will address business user questions?**
- **Who will administer user accounts?**
- **Who is the point person/team with Managed Services and Vault Support?**
- **Who will build new functionality into the system?
What is the process?**
- **Who owns training?**



Keys to Success

Planning

- Understand your starting point, including people and process
- Set goals
- Regularly assess your goals



Scope

- Build a solid foundation
- Slowly add more pieces when ready and as needed



Training

- Fundamental training
- Phased approach
- Role-based



Deployment

- Limit the initial deployment
- Feedback and refinement strategy
- Support structures and processes in place





Questions



Thank You

Complete the session survey with the Veeva app

Thank you

Search "Veeva" in app store
Password: rdsummit

