Housekeeping

- This session will be recorded and made available to all registrants
- All recordings will be available on demand via a link sent following each event
- The Certificate of Attendance will be provided within 7 days of this session
- Registrants must attend at least 1 eTMF Bootcamp session to receive the certificate

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Other Bootcamp Sessions

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Session 5

Janine Penman, Managing Director, JPScientific

Oliver Pearce, Commercialization Director, Montrium

Bringing TMF Management In-House in 2021: The Year of the Sponsor eTMF

May 6th @ 10am EST
(7am PST / 4pm CET)

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Session 6

Stephanie Viscomi, Associate Director, TMF Operations, Alexion

Paul Fenton, President & CEO, Montrium

How to Manage a Multi-Vendor eTMF Ecosystem Effectively.

May 25th @ 10am EST
(7am PST / 4pm CET)

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Your speakers today

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Agenda

- Where is the industry today with eTMF
- Traditional vendor selection pitfalls
- Steps to searching for & selecting an eTMF provider
- The Fast-Track eTMF Implementation Methodology
- Conclusion

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Part 1

eTMF Industry Trends

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TMF Maturity Progression

Archive

- Electronic archive of documents
- Easier access for business users
- Standardized structure and management
- Centralized management and maintenance
- Well managed, AFTER document completes business process
- Minimal transition from paper to electronic documents
- Strong Scanning / Indexing reliance

Active

- System drives business processes
- Business users rely on system for all content needs
- Structure flexibility for trial requirements
- Improvements driven by central metrics
- Doc mgmt DURING business process (i.e. Site Readiness)
- Clin Systems integration for consistent metadata
- E-workflow for internal review / approval
- Moderate transition from paper to e-docs

Integrated

- Process and users fully integrated
- eProcess all content – create / review / approve / final
- Inspection readiness embedded in all user behaviors
- Data driven trial milestone signals
- Full integration with internal systems
- All required docs signed electronically (digital signatures)
- Transition from managing documents to managing data

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POLL

Which stage of maturity is your organization in?

a) Archive

b) Active

c) Integrated

eTMF Value Creation

- Baseline is Compliance
- Evolve to Active management of eTMF for efficiency
- Inspection Ready at all times
- CRO in Sponsor eTMF system/processes more common
- Focus on establishment of/integration with eISF
- Remote access & review processes driven by COVID

Part 2

How to Accelerate eTMF Vendor Selection

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How have we selected vendors before?

Lengthy vendor evaluation processes

Large lists of vendors to evaluate

Complex RFI & RFP projects

Too much data to evaluate effectively

Focusing too much on Eutopia

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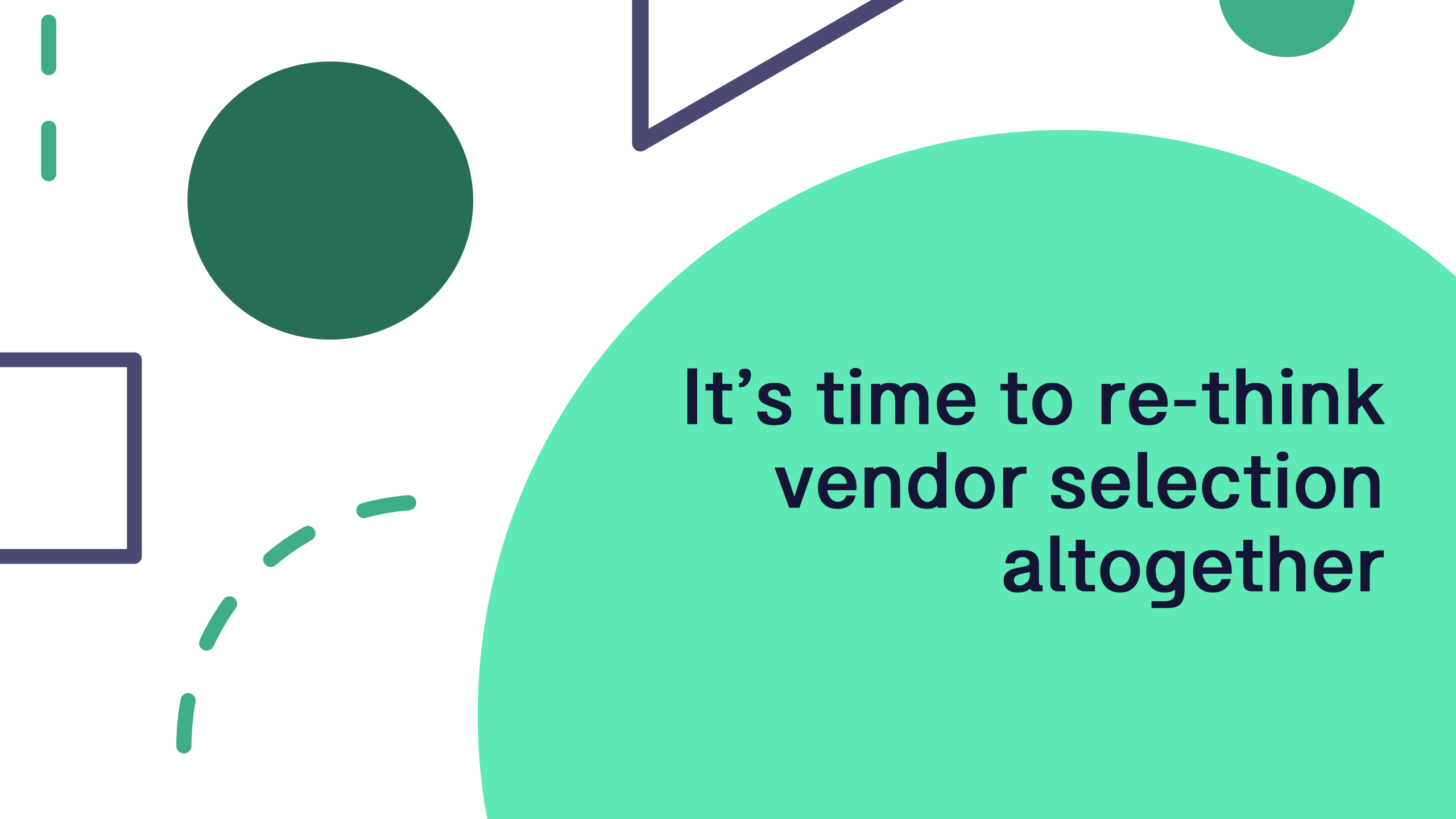# Why do so many still do it this way?

- "We've always done it this way"

- "Our SOP instructs us to evaluate vendors/systems like this"

- "If we don't follow our process, we may select the wrong vendor"

- "We're buying a system for the long term, we need to spend time making sure we are making the right choice"

POLL

How long should it take to evaluate and select an eTMF vendor?

a) Under 3 months

b) 3-6 months

c) 6-12 months

d) However long it takes

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It's time to re-think vendor selection altogether

7 Steps to Lean eTMF Vendor Selection

1 → **2** → **3** → **4** → **5** → **6** → **17**

Know your objective and clearly define what you're trying to achieve	Identify core system requirements & business processes for short-mid term	Decide on your vendor evaluation approach (formal vs informal)	Survey market and identify list of vendors (max 3-5)	Be clear about your requirements, budgets and who you're evaluating with each vendor	Score each vendor based on demonstrations, documentation provided and team fit	Select the vendor that meets your functional, fiscal and fundamental requirements

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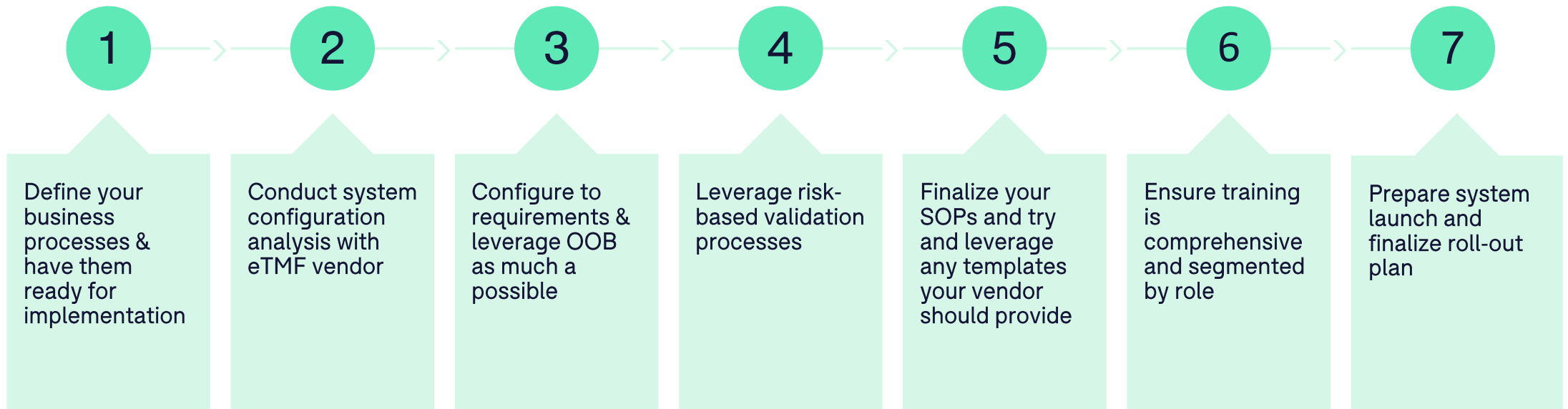eTMF
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Recommendations for Success

- Make your decision based on realistic system maturity needs for a 2-3 year window

- Is platform vs eTMF best of breed impactful?

- Prioritize near term features versus aspirational, in order to assess fit appropriately

- Ensure the vendor you select is a good culture fit with your team

- Leverage available material such as audit reports, compliance documentation, case studies, online reviews & peer feedback to avoid lengthy due diligence

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The Fast-track eTMF Implementation Methodology

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Fast-track eTMF Implementation Methodology

1 → **2** → **3** → **4** → **5** → **6** → **7**

1 — Define your business processes & have them ready for implementation

2 — Conduct system configuration analysis with eTMF vendor

3 — Configure to requirements & leverage OOB as much a possible

4 — Leverage risk-based validation processes

5 — Finalize your SOPs and try and leverage any templates your vendor should provide

6 — Ensure training is comprehensive and segmented by role

7 — Prepare system launch and finalize roll-out plan

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How to Implement Successfully with Speed

- Have your business processes and operating models well defined, before starting vendor configuration workshops

- Default to the OOB, unless there is a true business/organizational factor driving customization

- Take a risk-based approach to Validation

- Training - should cover process, SOP and system in a role-based approach

- Plan deployment strategy – New Studies only, all studies

In conclusion

- Don't overcomplicate your vendor selection process

- Focus on what is important now and the near-term

- Have a good understanding of your requirements, and processes as this speeds up selection & implementation

- Take a risk-based approach wherever possible

- Work with vendors that understand your business

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