

Presented by

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Switching gears, why upgrading your eTMF can lead to better outcomes

montrium

Agenda

- About Zydus
- Challenges
- eTMF Vendor Selection
- Implementation of eTMF
- Results Post Implementation
- Lessons Learned
- What's Next for Zydus



About Zydus Therapeutics, Inc.

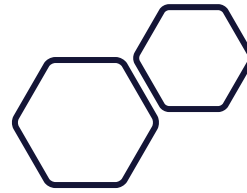
Vision

- Zydus Therapeutics Inc is a life-sciences company backed by pathbreaking scientific research and technological innovations, done with the patient in mind powered by excellence in quality and a digital first approach that offers access to life-saving & life-changing solutions & addresses unmet healthcare needs to empower lives, by helping people discover well-being & good health.

Purpose

- Empowering Lives Through Science & Innovation

More About Zydus



- Zydus Therapeutics, Inc. (ZTI) is headquartered in Pennington, NJ
- ZTI Studies
 - Phase 1, Phase 2, and Phase 2-B US studies are managed (for the most part) internally. We partner with local CRO's from these countries to manage our X-US sites.
- The ZTI Team
 - Our 'can-do' clinical operations team has grown from two in 2015 to approximately 30 in 2022.



Challenges - Zydus

- **Challenge #1:** Quickly gauging the status/health of our eTMF
 - Spent a great deal of time on relatively routine tasks and trying to avoid duplicating tasks
- **Challenge #2:** Efficiency and productivity
 - Tried to be proactive in establishing safeguards, identifying issues, and creating plans to fix the issues
- **Challenge #3:** Transitioning to consistently proactive approaches in what felt like a 'reactive' environment
 - Searched for a vendor that understood both the client and the industry

eTMF Vendor Selection - Zydus

- How can this product improve our document management?
 - Validated
 - More efficient/faster
 - Cost effective (Time is money!)
 - User-friendly with powerful features
- Looked to implement a better way to internally manage essential study documents in accordance with the industry standard TMF Reference Model
- Began vetting a range of platforms from multiple vendors
- Looked for vendors who not only knew their product, but who
- Wanted an opportunity for a test-drive the product 'Sand-Box'.

Montrium Vendor Selection Support



**Deep Dive
Discovery Call**



**Product
Demonstrations**



Sandbox



**Implementation,
Financial Estimates
& Formal Proposal**

ZyduS Sandbox



Sandbox Training



Detailed Instructions – Connect Help Center



Added extra users



Time extension for further testing



Exercises for ZyduS specific use cases

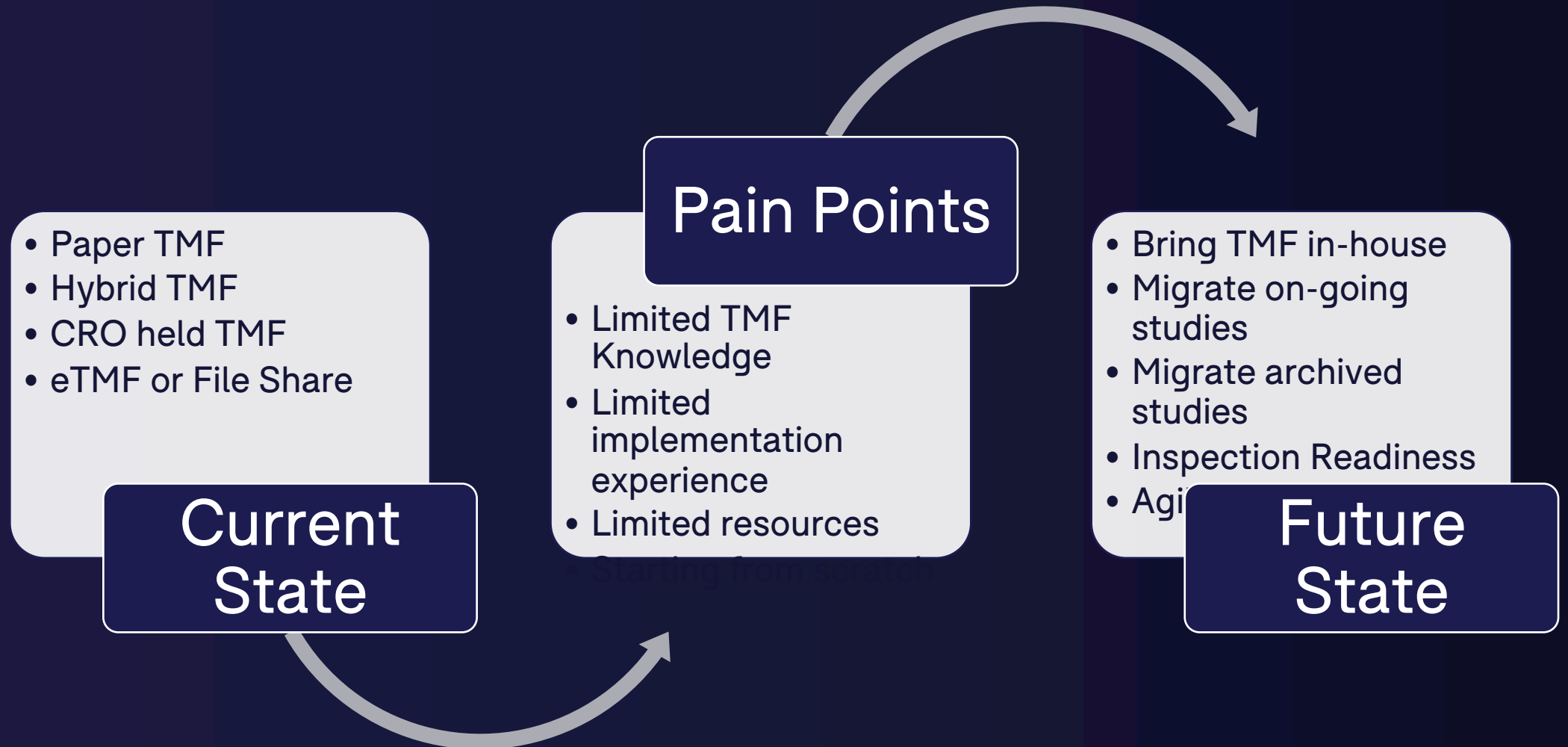


Feedback sessions

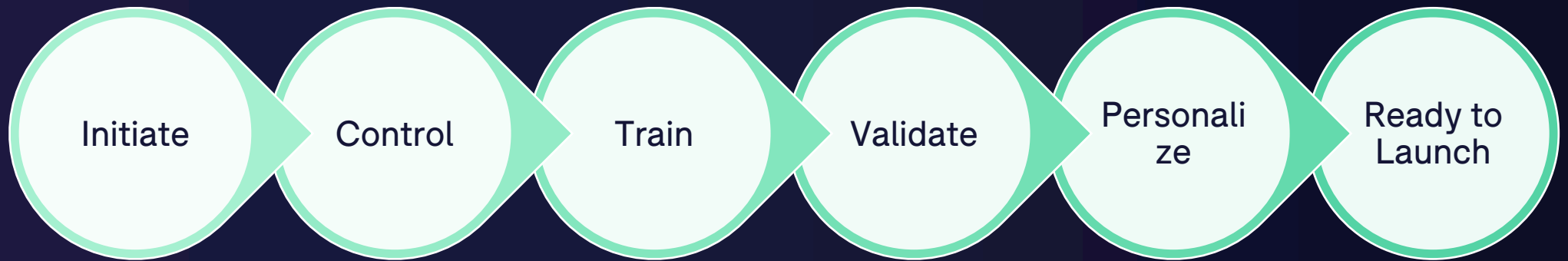
Extension of your team



TMF 1.0 ▶ 2.0



Montrium Implementation Roadmap



Recommended Approach to Onboarding (avg. 4-8 weeks)

Assumes a risk-based approach to user acceptance, leveraging Montrium's internal testing and qualification



Zydus eTMF Implementation Timeline



Implementation - Zydus

Montrium set us up with a Project Manager

Our team of 4 Super Users attended a 16-week intensive onboarding plan

Plan for kick-off and post-going live with regular 1:1 client and PM meetings

Our very dedicated Montrium PM ensured the 'Train the Trainer' approach would be successful

Result - Zydus

From May-Aug 2021:
Initiated newly approved
study in eTMF Connect

- 4 Super Users, 4 End Users, and 1 Quality person to review all study and site-level documents

By December 2021:
Approximately 15 sites
initiated

- 6 Super Users, 7 End Users, and an X-US CRO successfully onboarded
- Over 1000 documents published

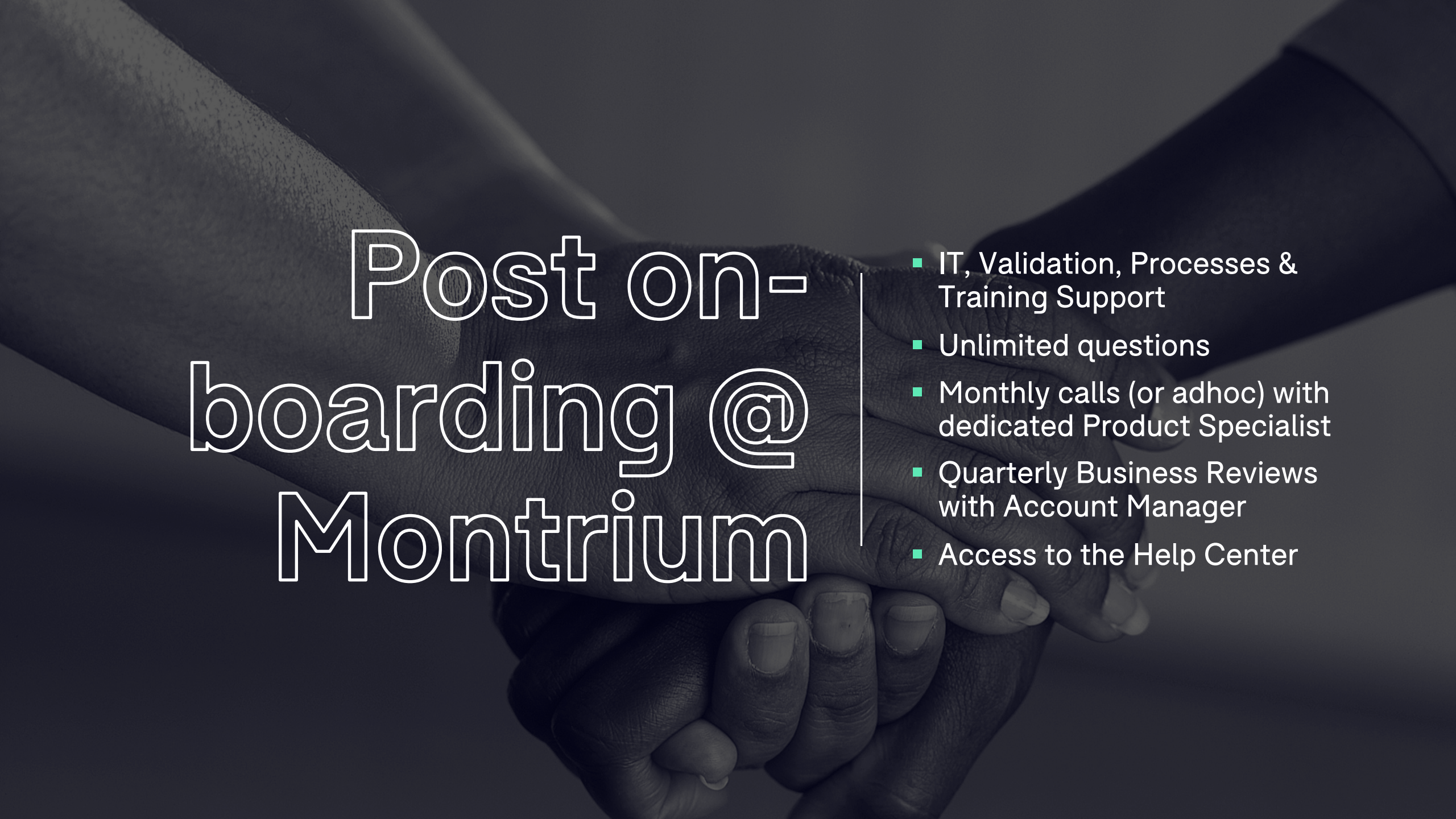
To date: More than tripled
the number of documents
archived and doubled the
number of users

Favourite feature: Inbound
Quality Review (IB-QC)

- Greatly reduced the number of documents rejected during the final Post-Approval QC review

Lessons Learned - Zydus

- Providing feedback to the Product Specialist goes directly to the product team and helps drive change in the system
- Regardless of how good a system is, it takes time to get used to the language (most systems use different terms)
 - The Montrium articles are helpful for users.
- Our team learned how to best utilize Connect Support/Help Center (e.g., screenshots are timesavers)
- eTMF Connect Fundamentals is a priceless tool



Post on-boarding @ Montrium

- IT, Validation, Processes & Training Support
- Unlimited questions
- Monthly calls (or adhoc) with dedicated Product Specialist
- Quarterly Business Reviews with Account Manager
- Access to the Help Center

What's Next for Zydus Therapeutics



CONTINUE TO IMPROVE ON HOW WE DO THINGS AND ENSURE ZYDUS IS AUDIT/INSPECTION-READY. LEARN MORE ABOUT MONTRIUM FEATURES WE HAVE YET TO UTILIZE.



METRICS! METRICS! METRICS! PLAN TO BETTER UTILIZE CONNECT SYSTEM TOOLS TO RUN METRICS ON MORE OF OUR ACTIVITIES AND GENERATING REPORTS FOR HIGHER-LEVEL MANAGEMENT USE



ADDITION OF MORE STUDIES AND SYSTEM USERS IN ETMF CONNECT.

