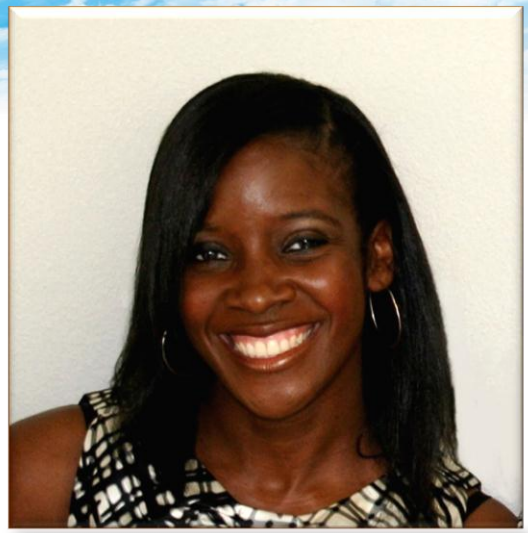
Process Redesign to Maintain Inspection Ready eTMFs

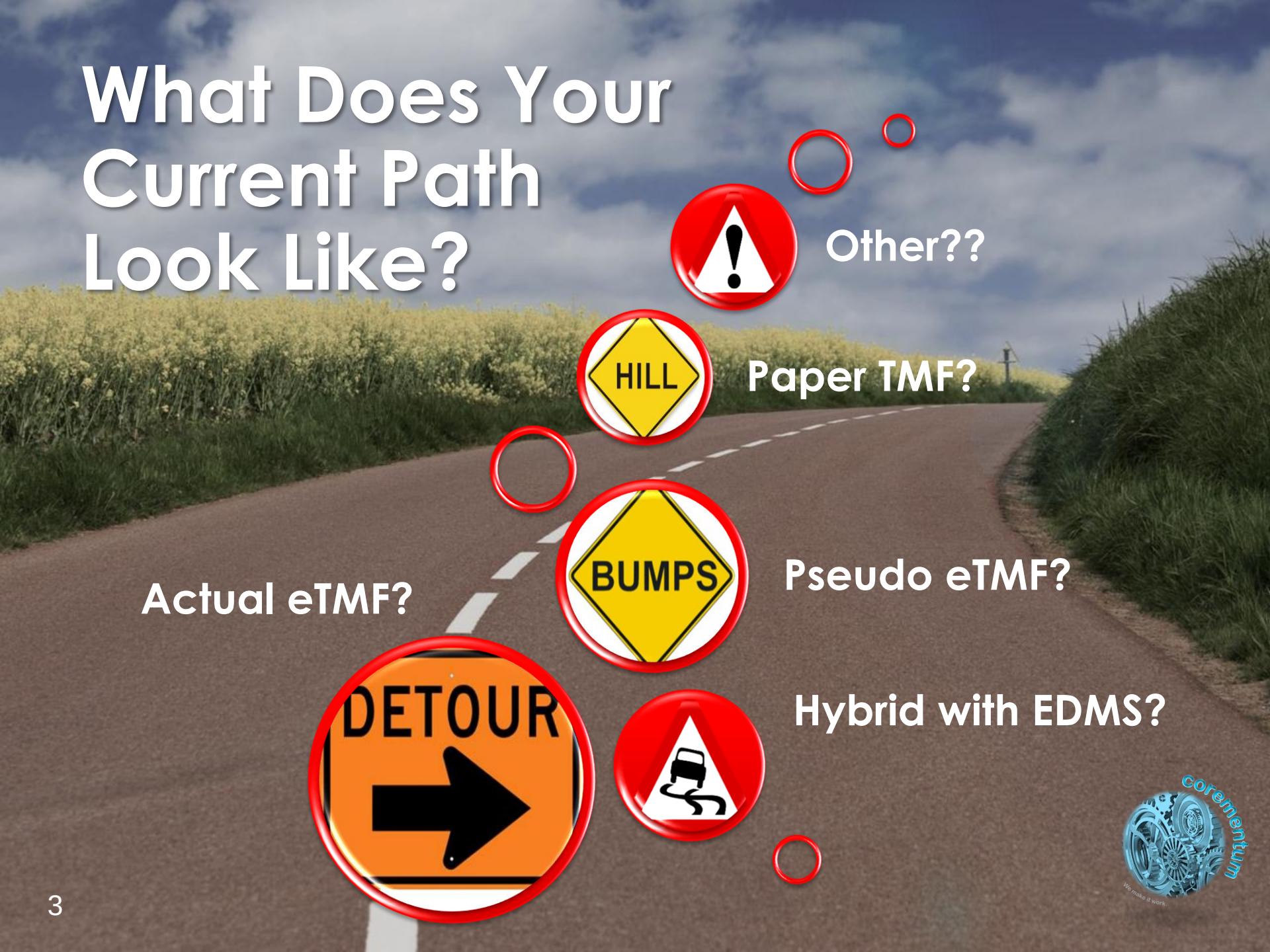
Tamika Jackson
Corementum



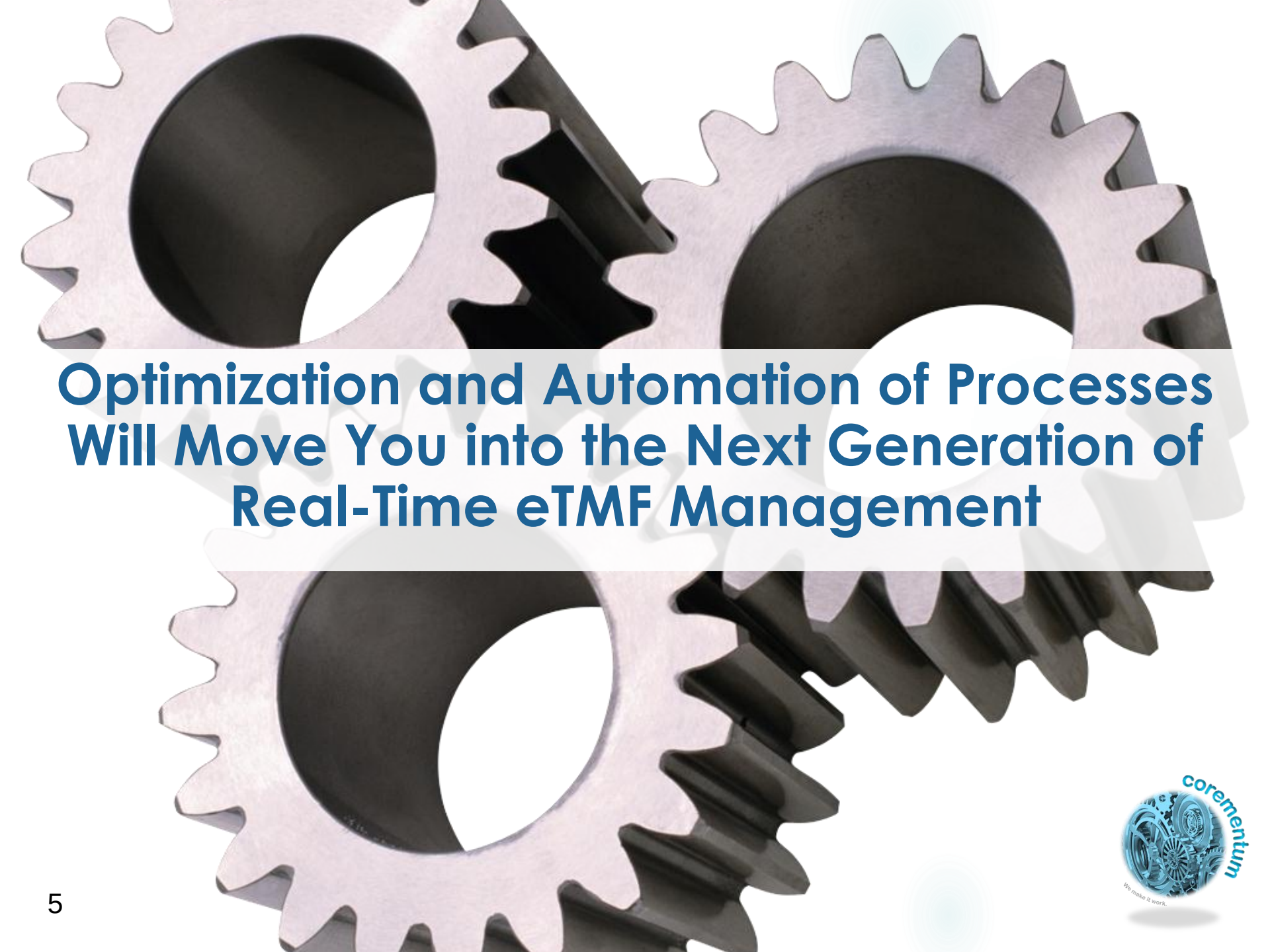
Process Redesign to Maintain Inspection Ready eTMFs

Tamika Jackson
President
Corementum
We make it work.

What Does Your Current Path Look Like?

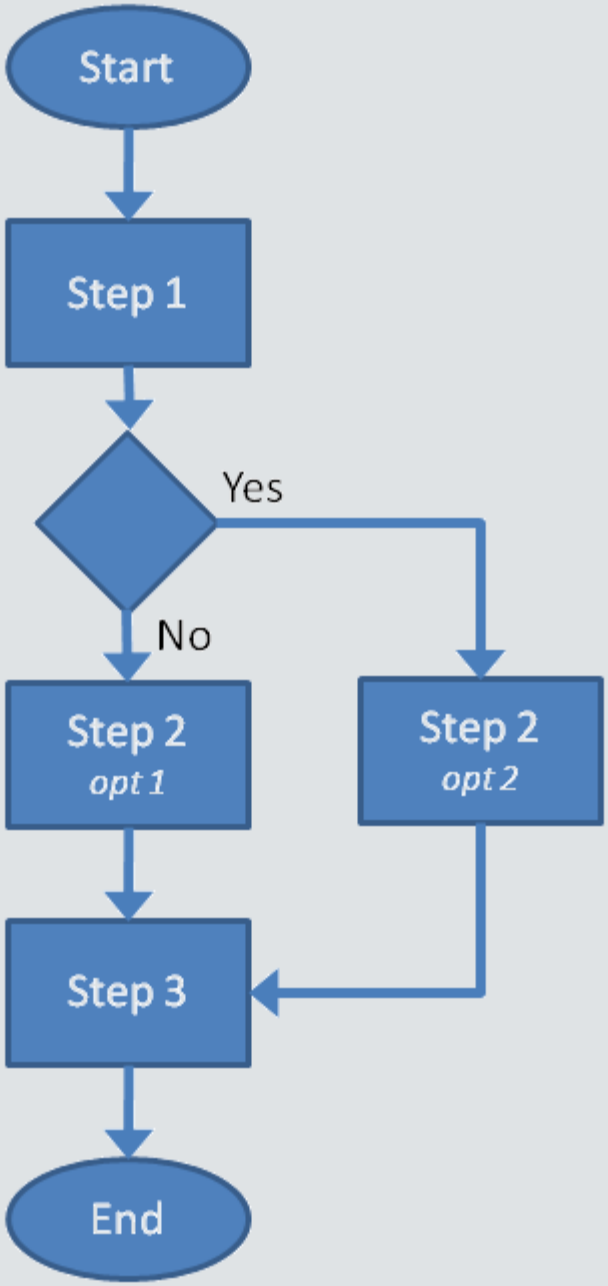


The eTMF Shift



Optimization and Automation of Processes Will Move You into the Next Generation of Real-Time eTMF Management

Technology
Alone Isn't
Enough



Clearly Defined Processes Alone Are Not Enough

Systems and Processes Must Not Only Coexist, but Must Create a Symbiotic Relationship

eTMF Management Process +
eTMF Management System =
eTMF Management Solution

So, how do we redesign processes to extract maximum value from our eTMF?

The 4 Tenets of a Successful eTMF Process Redesign

Adopt DIA TMF Reference Model

Build a Repeatable Framework

Redesign Current Processes

Define TMF Inspection Readiness Checks

Adopt the DIA TMF Reference Model

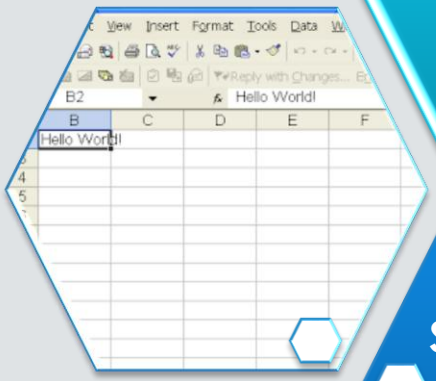
TMF Reference Model

Zone	Section		Artifact name	
gement	05.02	Site Set-up Documentation	05.02.07	Site and Staff Qu Supporting Infor
gement	05.02	Site Set-up Documentation	05.02.08	Form FDA1572
gement	05.02	Site Set-up Documentation	05.02.09	Investig eg Agreement

DIA TMF Reference Model

Benefits of Adopting

Eliminates variability for inspections



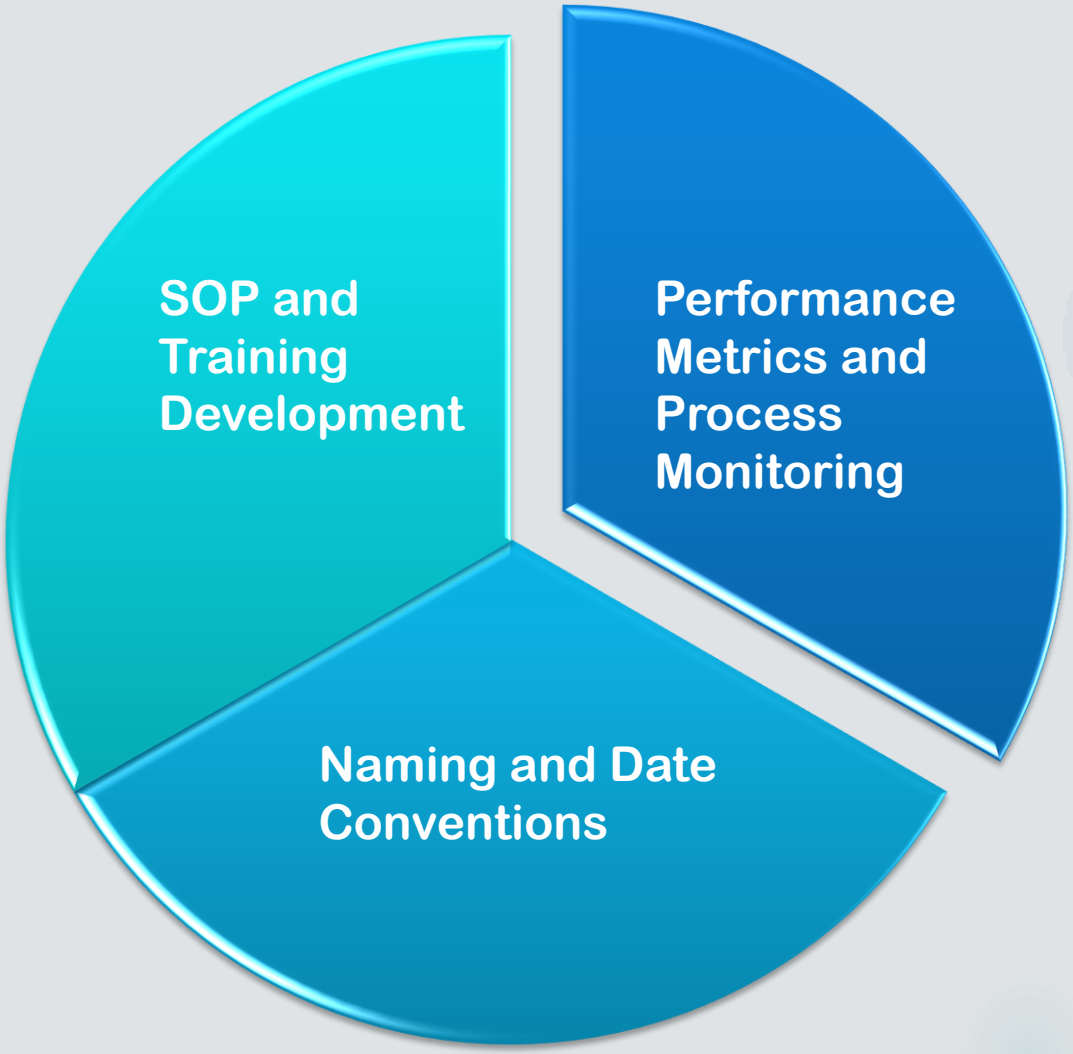
Standardizes collection & management for all parties

Facilitates acquisitions, joint ventures, partnerships

Single, unified list of TMF artifacts

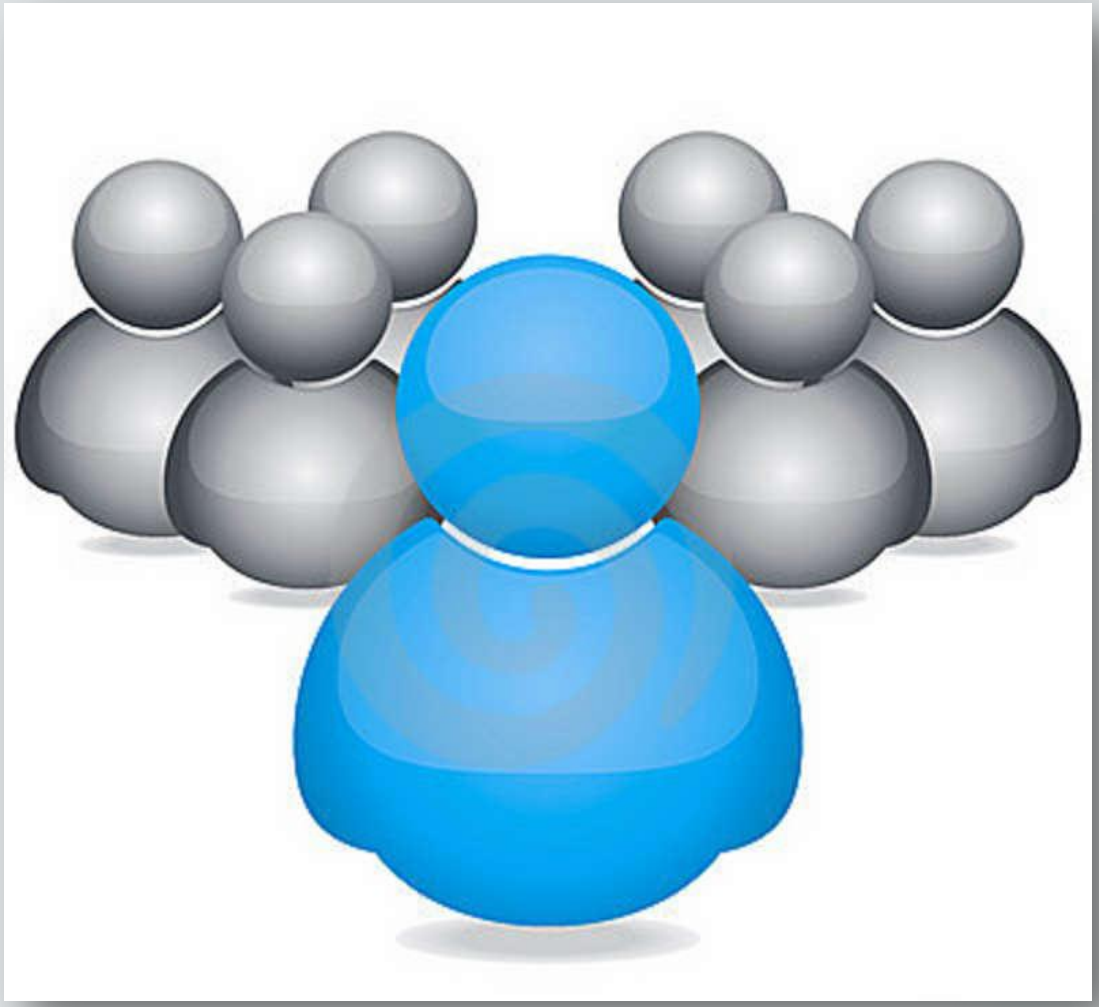
DIA TMF Reference Model

Adoption Best Practices

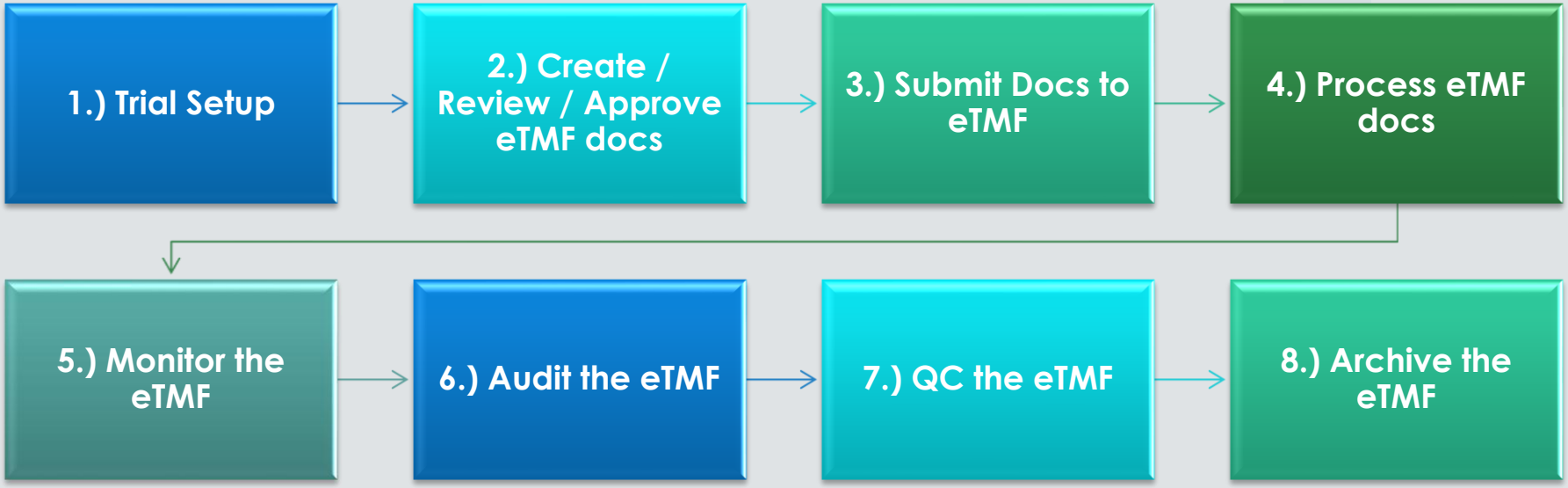


2 Build a Repeatable Framework

STEP 1: Identify TMF Roles and Responsibilities



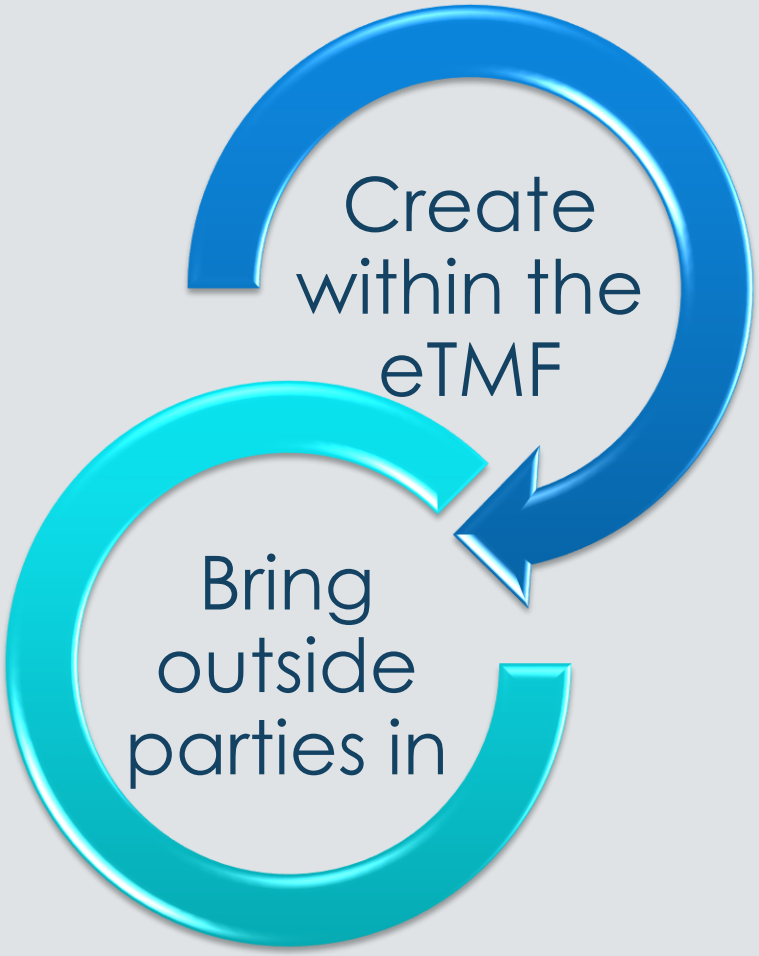
STEP 2: Complete the Traditional eTMF Management Lifecycle Process



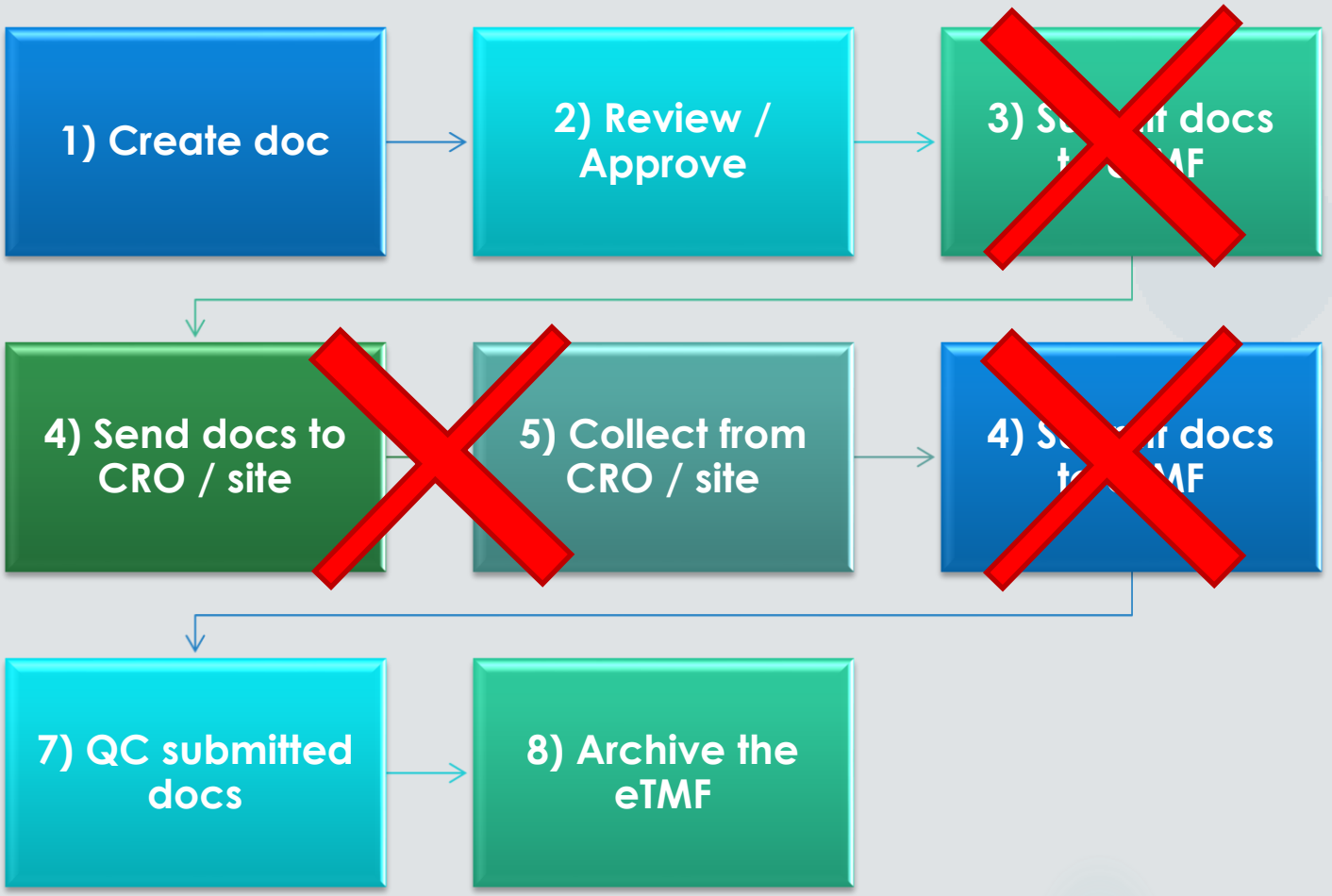
OR...

Redesign Traditional eTMF Processes

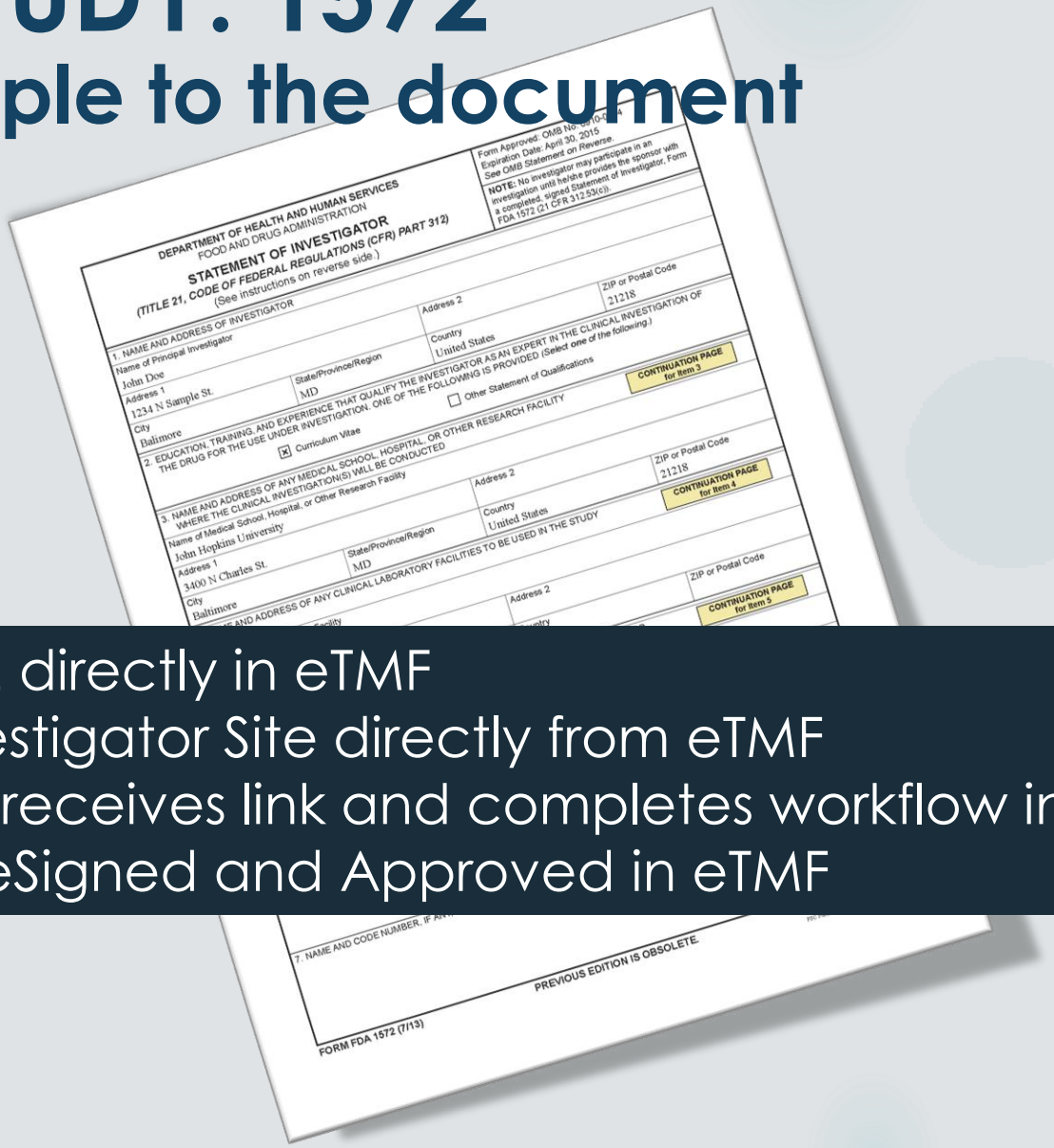
Step 1: Make the Processes More Efficient



Step 2: Modern eTMF Management Lifecycle Process



CASE STUDY: 1572
Bring people to the document


DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

STATEMENT OF INVESTIGATOR
(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312)
(See instructions on reverse side.)

Form Approved: OMB No. 0910-0014
Expiration Date: April 30, 2015
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR
Name of Principal Investigator: John Doe
Address 1: 1234 N Sample St.
Address 2:
City: Baltimore
State/Province/Region: MD
Country: United States
ZIP or Postal Code: 21218

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED (Select one of the following.)
☒ Curriculum Vitae
☐ Other Statement of Qualifications
CONTINUATION PAGE for Item 3

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED
Name of Medical School, Hospital, or Other Research Facility: John Hopkins University
Address 1: 3400 N Charles St.
Address 2:
City: Baltimore
State/Province/Region: MD
Country: United States
ZIP or Postal Code: 21218
CONTINUATION PAGE for Item 4

4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY
Address 2
ZIP or Postal Code
CONTINUATION PAGE for Item 5

7. NAME AND CODE NUMBER, IF ANY

PREVIOUS EDITION IS OBSOLETE.

FORM FDA 1572 (7/13)

- Create 1572 directly in eTMF
- Send to Investigator Site directly from eTMF
- Investigator receives link and completes workflow in eTMF
- Document eSigned and Approved in eTMF

CASE STUDY: Contracts

Step 3: Operationalize your SOPs by building them into the system

Build in Quality and Inspection Readiness Checks

eTMF Document QC Process

How to QC the eTMF Documents

- **eTMF Document QC Process:**

  Build the TMF Document QC Process as a QC check to be completed prior to each document approval

- **Document QC Check**
  - ✓ Required TMF Document for the study?
  - ✓ Legible?
  - ✓ Complete?
  - ✓ Signed and dated (if applicable)?
  - ✓ Translations available?

Identify eTMF Milestones

How to QC Your eTMF

eTMF Milestones:

Trigger events or study stages marking the start of a set timeframe during which all relevant documents must be made available within the TMF

Apply RUTOLA

- ✓ **R**etrievable
- ✓ **U**nique
- ✓ **T**ranslations
- ✓ **O**riginal
- ✓ **L**egible
- ✓ **A**pplicable

How to QC Your eTMF

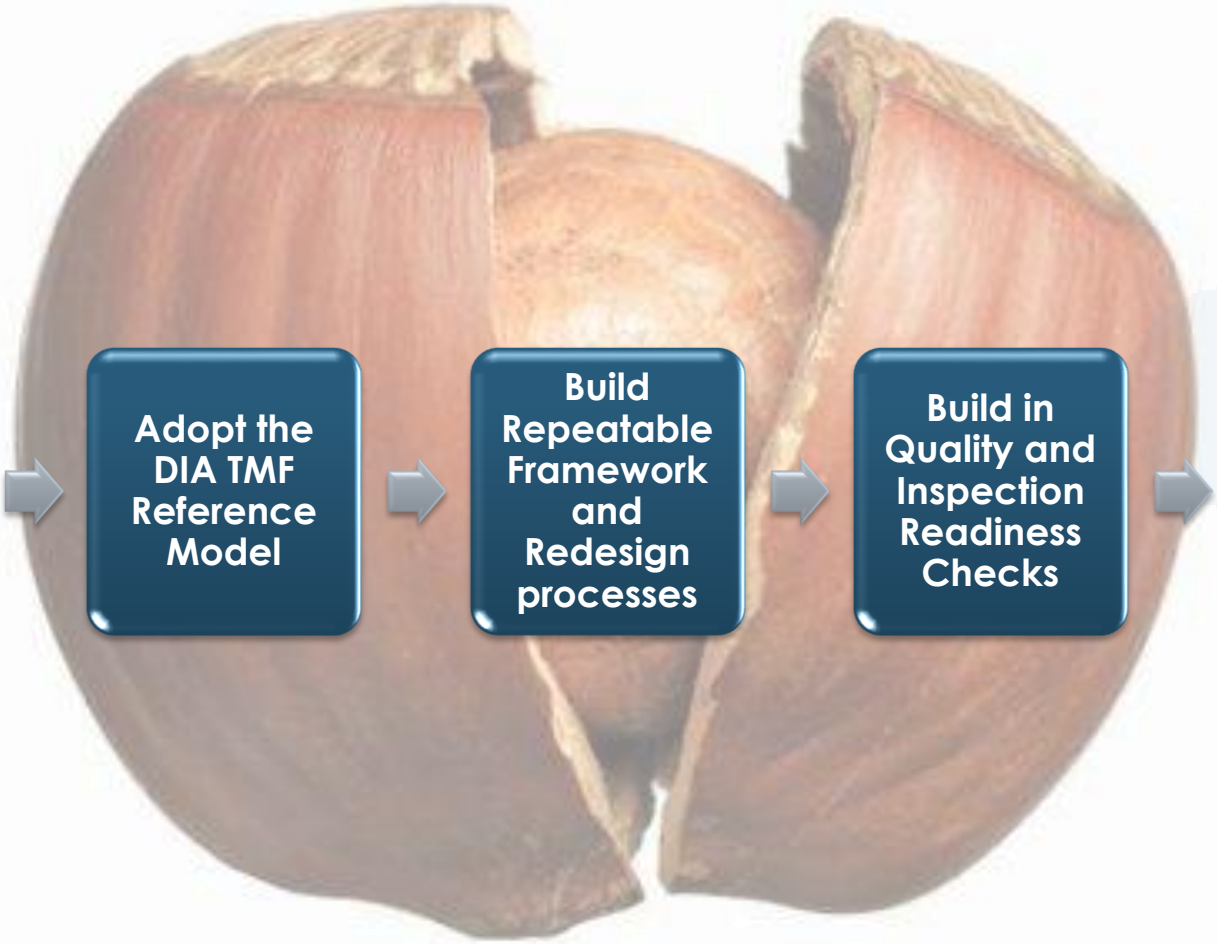
Site Initiation (eTMF Milestone)

The date the Sponsor permit the investigator site to begin recruiting subjects for the study

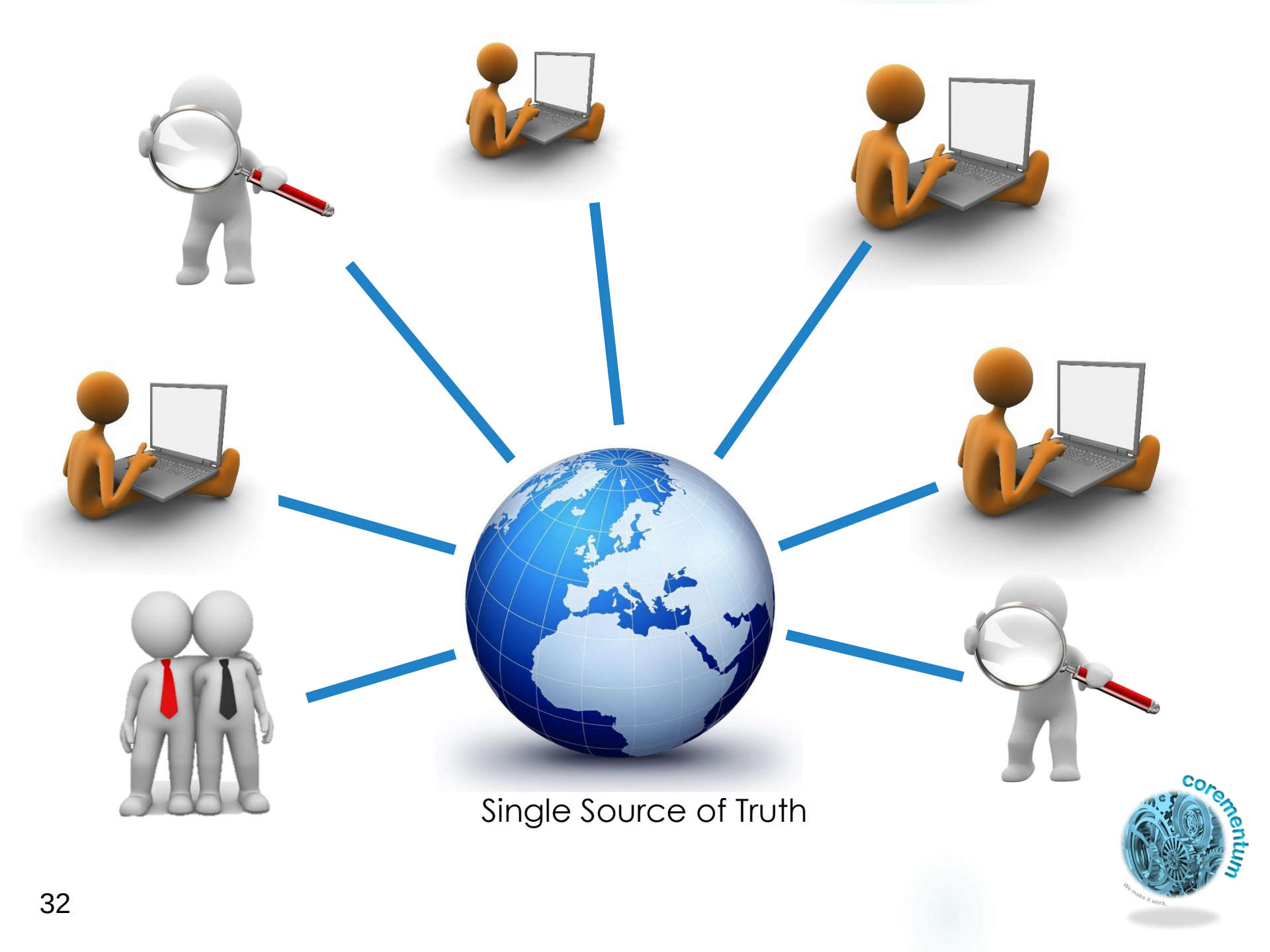
Document Examples

- ✓ Investigator Brochure (ICH E6 8.2.1)
- ✓ Protocol (ICH E6 8.2.2)
- ✓ Informed Consent Form (ICH E6 8.2.3)

In a nutshell …



- Drive the System from a Process Perspective
- Adopt the DIA TMF Reference Model
- Build Repeatable Framework and Redesign processes
- Build in Quality and Inspection Readiness Checks
- Maximize Your Ability to Increase Visibility, Access, and Value


Single Source of Truth

If you don't have time to **DO IT RIGHT**, when will you have ***TIME*** to **do it over**?

Thank you!