

ENNOV SOFTWARE FOR LIVE

PRODUCT DIRECTOR, CTMS

24 Years of experience in software for Life Sciences working with over 80 pharma, biotech, CRO and Med Device companies in the US, Europe, Japan and Israel

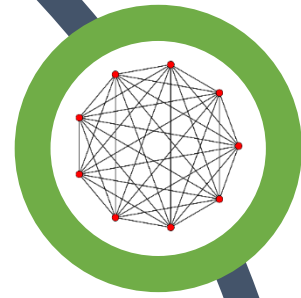
Formerly:

- VP of Product Management for Wingspan (later IQVIA) for eTMF, eREG (Regulatory EDMS), ePROMO (Promotional Materials Management)
- Director of Product Management for NextDocs (Regulatory and Quality EDMS)
- Director of Professional Services for GlobalSubmit (eCTD publishing, validation and viewing tools used by FDA and sponsors)

Member of the TMF Reference Model Steering Committee



AGENDA



01 – THE ECLINICAL UNIVERSE

Component systems, adoption



02 – UNIFICATION – WHAT DOES IT MEAN?

Definition, difference between unification and integration, solution touch points



03 – UNIFICATION – A PRACTICAL APPROACH

Where to start, expected benefits, use cases, decision-making framework, important elements of solution



04 - SUMMARY

Points to consider

eClinical Universe – the Components

Site



- Study Startup
- Investigator / Site Portal
- eISF
- IVRS/ RTSM/ IRT
- eConsent
- Financial/Grants / Payments
- eLearning
- Contracts

Clin Ops



- CTMS
- eTMF
- RBM
- eArchive
- QMS
- Study Design / Optimization
- Investigator DB
- Endpoint Adjudication
- Centralized Monitoring

Regulatory



- Clinical Trial Registries
- Safety/PV
- RIM
- Regulatory Publishing Intelligence

Patient

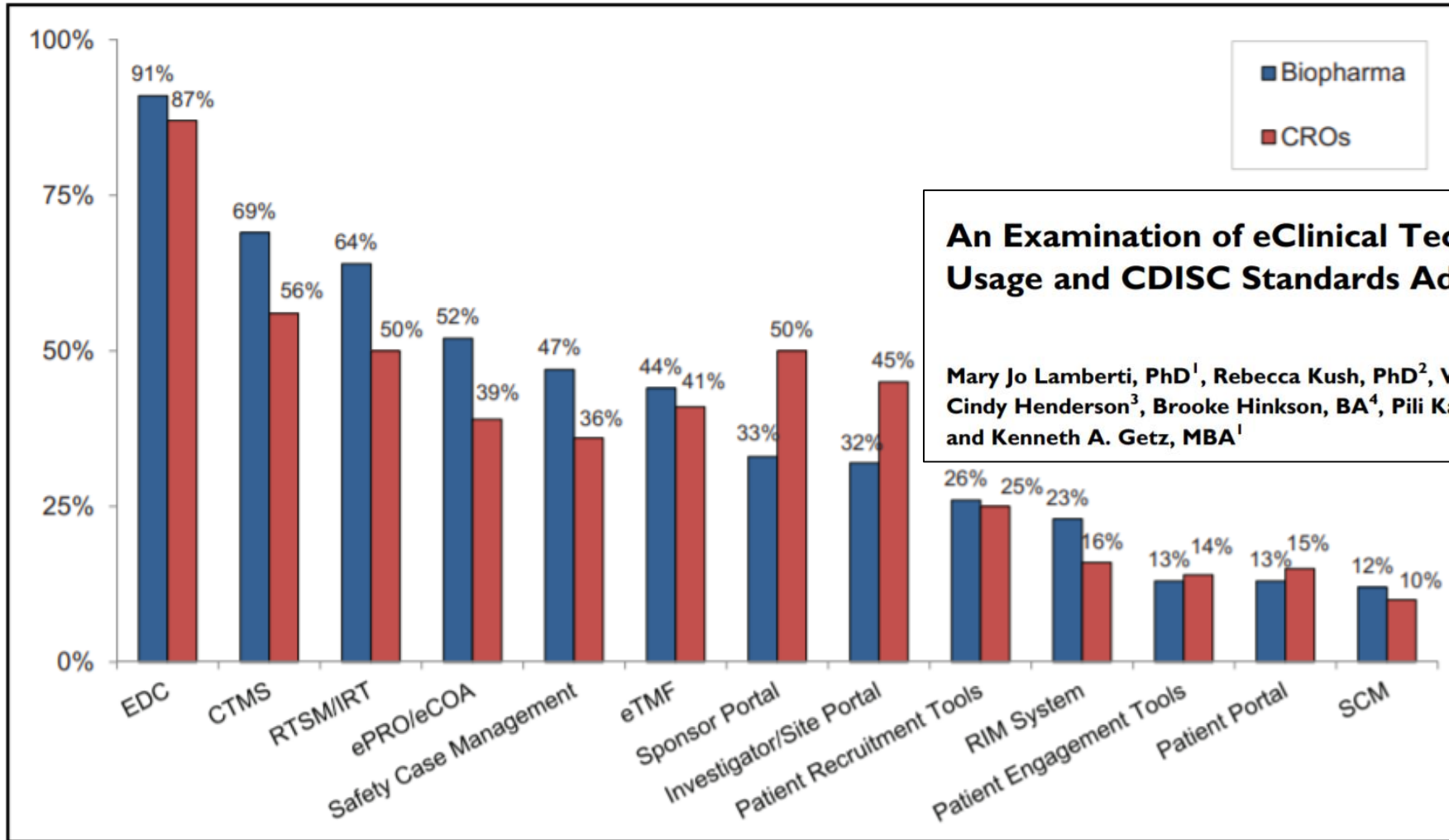


- ePRO/eCOA
- EMR/EHR
- Patient Recruitment
- Patient Portal
- Reimbursement
- Wearables

Data Mgmt



- Clinical Data Warehouse
- eSource
- EDC / CDMS
- Master Data Management

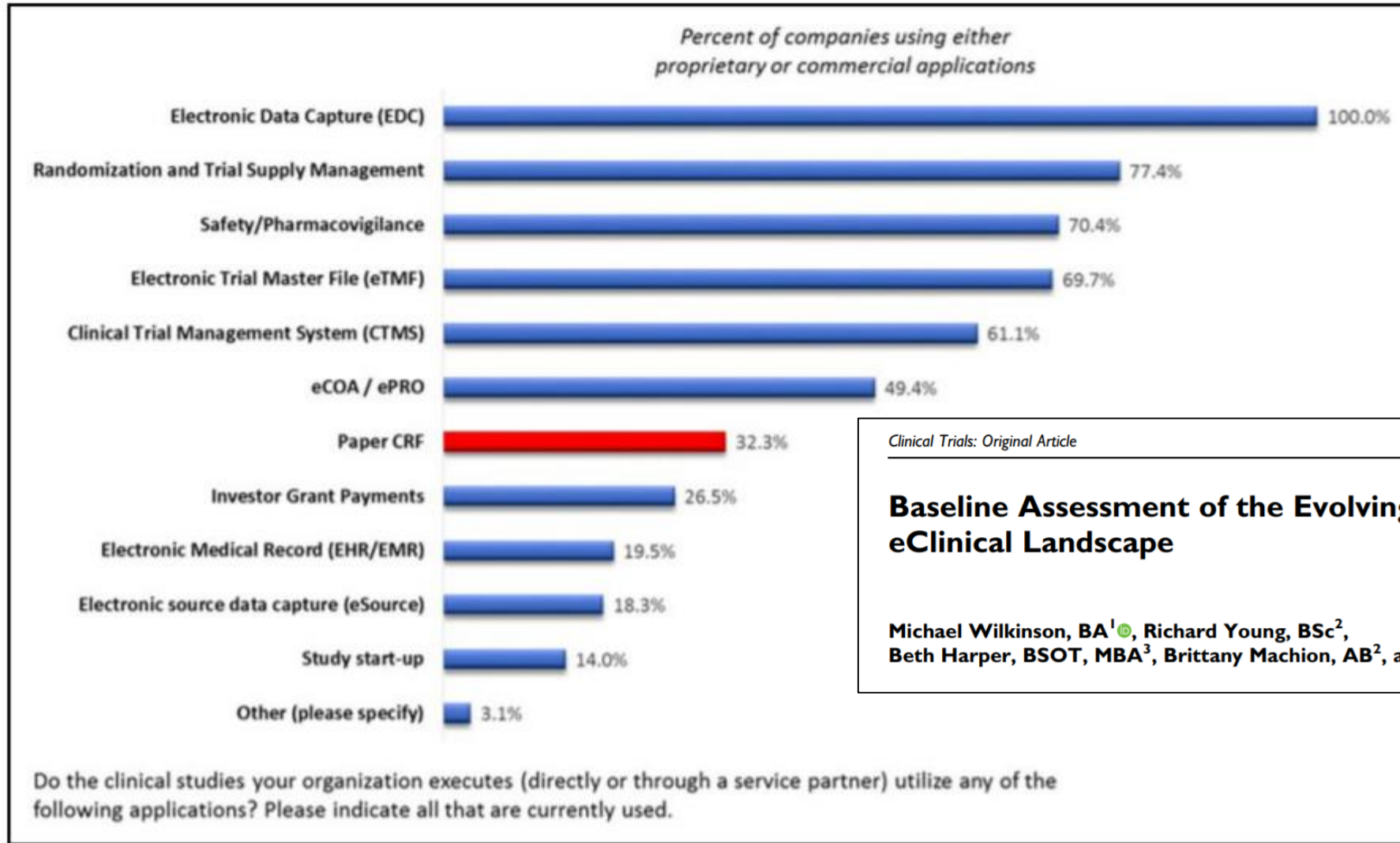


An Examination of eClinical Technology Usage and CDISC Standards Adoption

Mary Jo Lamberti, PhD¹, Rebecca Kush, PhD², Wayne Kubick, MBA², Cindy Henderson³, Brooke Hinkson, BA⁴, Pili Kamenju, MPH¹, and Kenneth A. Getz, MBA¹

Therapeutic Innovation & Regulatory Science
2015, Vol. 49(6) 869-876
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DOI: 10.1177/2168479015586003
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Figure 1. Current usage of eClinical trial technology tools by sponsors and contract research organizations (n = 318).



DIA

Clinical Trials: Original Article

Baseline Assessment of the Evolving 2017 eClinical Landscape

Therapeutic Innovation & Regulatory Science
 2019, Vol. 53(1) 71-80
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 DOI: 10.1177/2168479018769292
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**Michael Wilkinson, BA¹, Richard Young, BSc²,
 Beth Harper, BSOT, MBA³, Brittany Machion, AB², and Ken Getz, MBA¹**

Figure 1. Clinical applications used.

2017 – Clinical Applications Used by Company Size

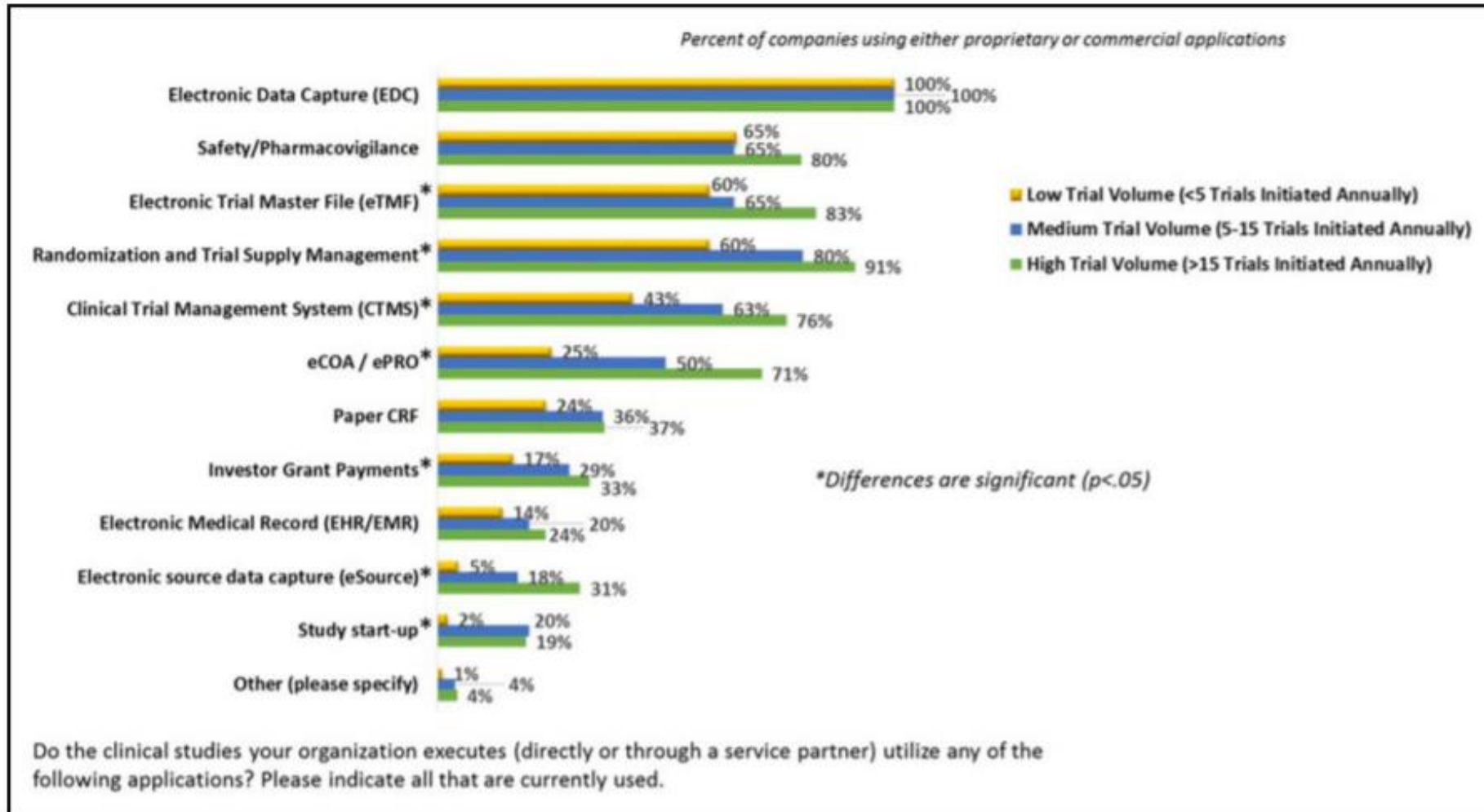
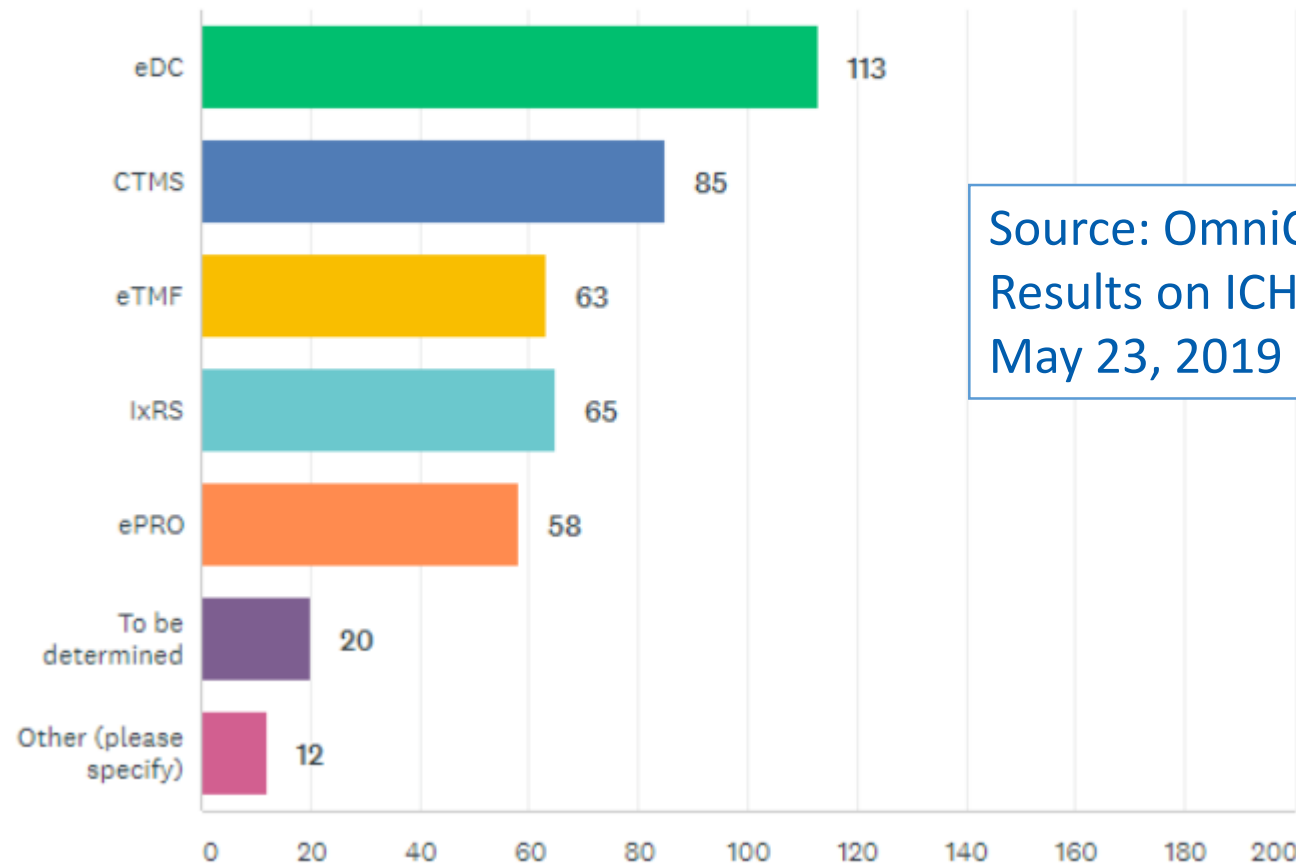


Figure 2. Clinical applications used by company size.

Most Critical eClinical Systems for Implementing ICH E6 (R2)

Q13. What are/will be the different data source systems that your organization considers essential to monitor data for implementing ICH E6(R2)? Select all that apply.



Source: OmniComm and eClinical Forum Release Survey Results on ICH-E6(R2) and RBM implementation, posted May 23, 2019

Definition of a Unified System

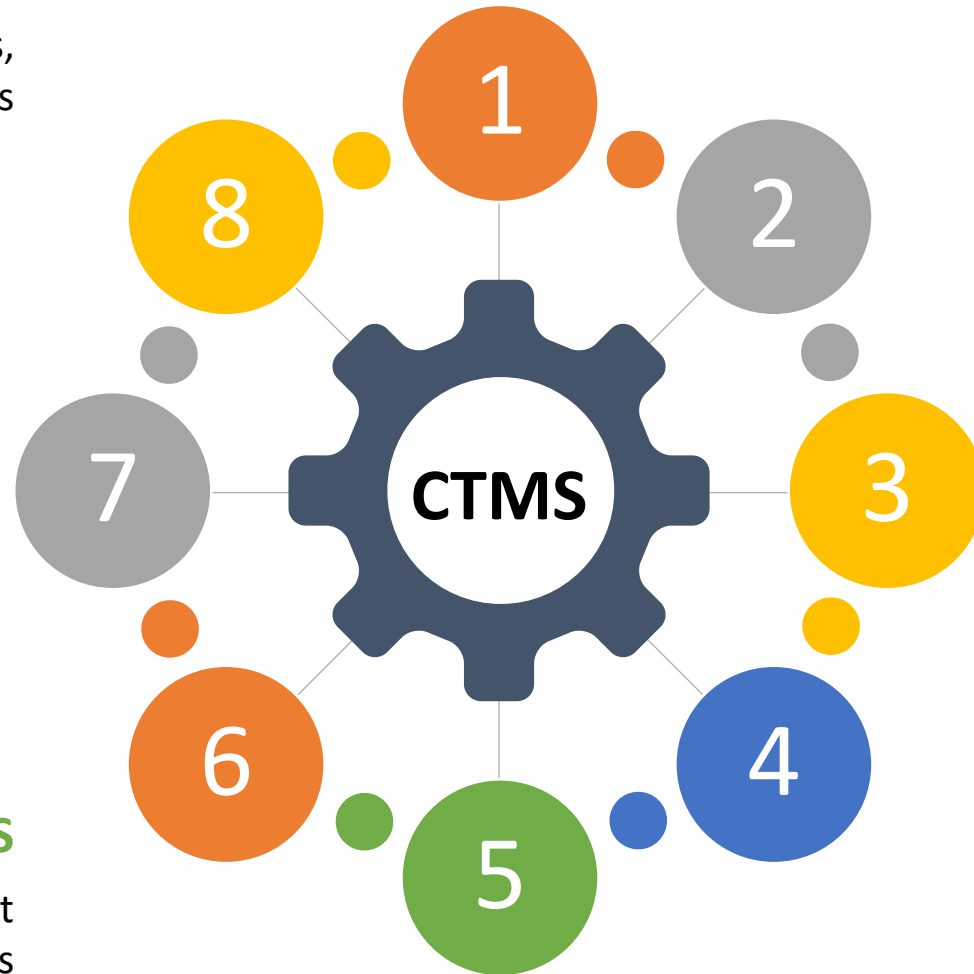
In a unified eClinical infrastructure, formerly disparate systems are merged.

Users no longer work in “CTMS” or “eTMF”, but in a harmonized clinical infrastructure where a single source of truth is a given, and changes and additions automatically impact the appropriate data, documents and processes.



eClinical Integration Points

Not Comprehensive: Choosing only the most important in a **CTMS-centric** view



8. EDC and ePRO

Subject info and status, queries, deviations, patient visits

7. Warehouses / MDM

Product, study, label, manufactures, metrics

6. eLearning

Training requirements, status, retraining.

5. QMS

Deviations, CAPAs, audit findings

1. eTMF

Trials, sites, investigators, visits, MVR documents, milestones, events

2. IRT

Shipping, dispensing, expiry, destruction, prediction

3. PV

SAEs, reporting status, safety letter distribution


4. RIM

New investigators, protocol updates, registry info, submission status, correspondence

Where to Begin? The Task is Overwhelming!

5 to 50
systems

More if counting paper/manual, outsourced systems...



Needs differ
by **country**
or **region**



Everyone has
legacy
systems



\$

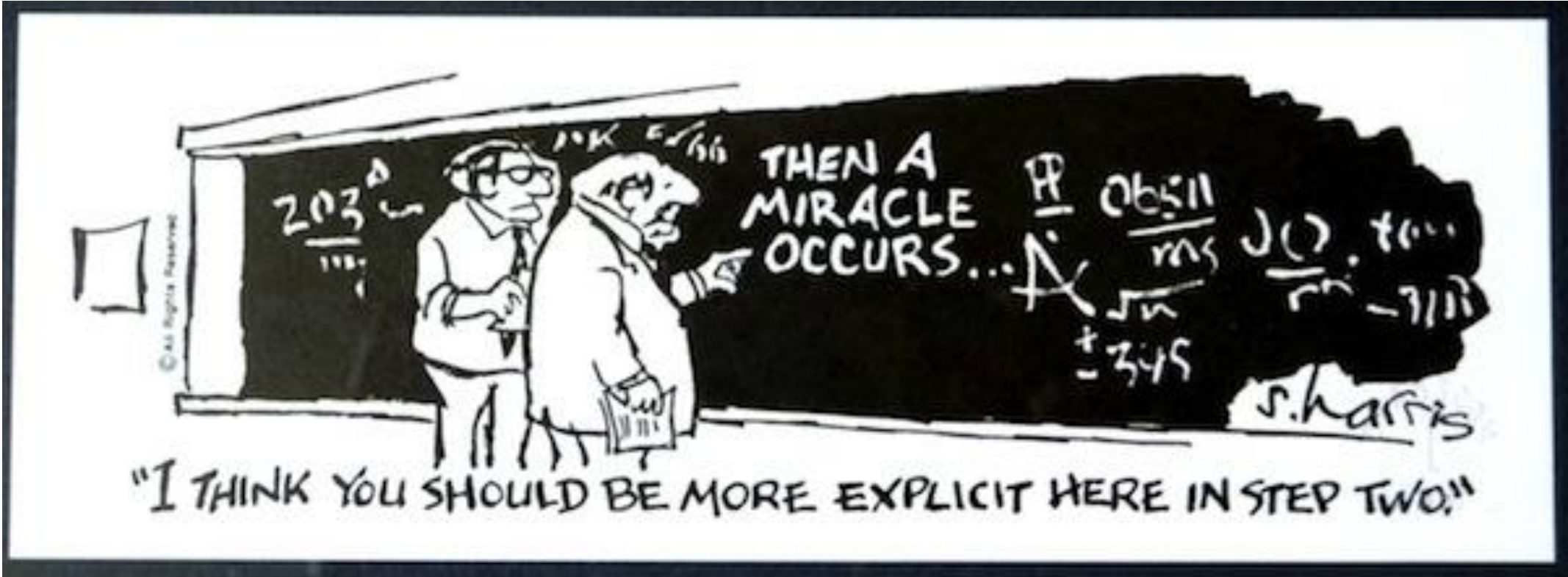
There is **never**
enough
budget to do
everything you
would like to do

N-dimensional problem

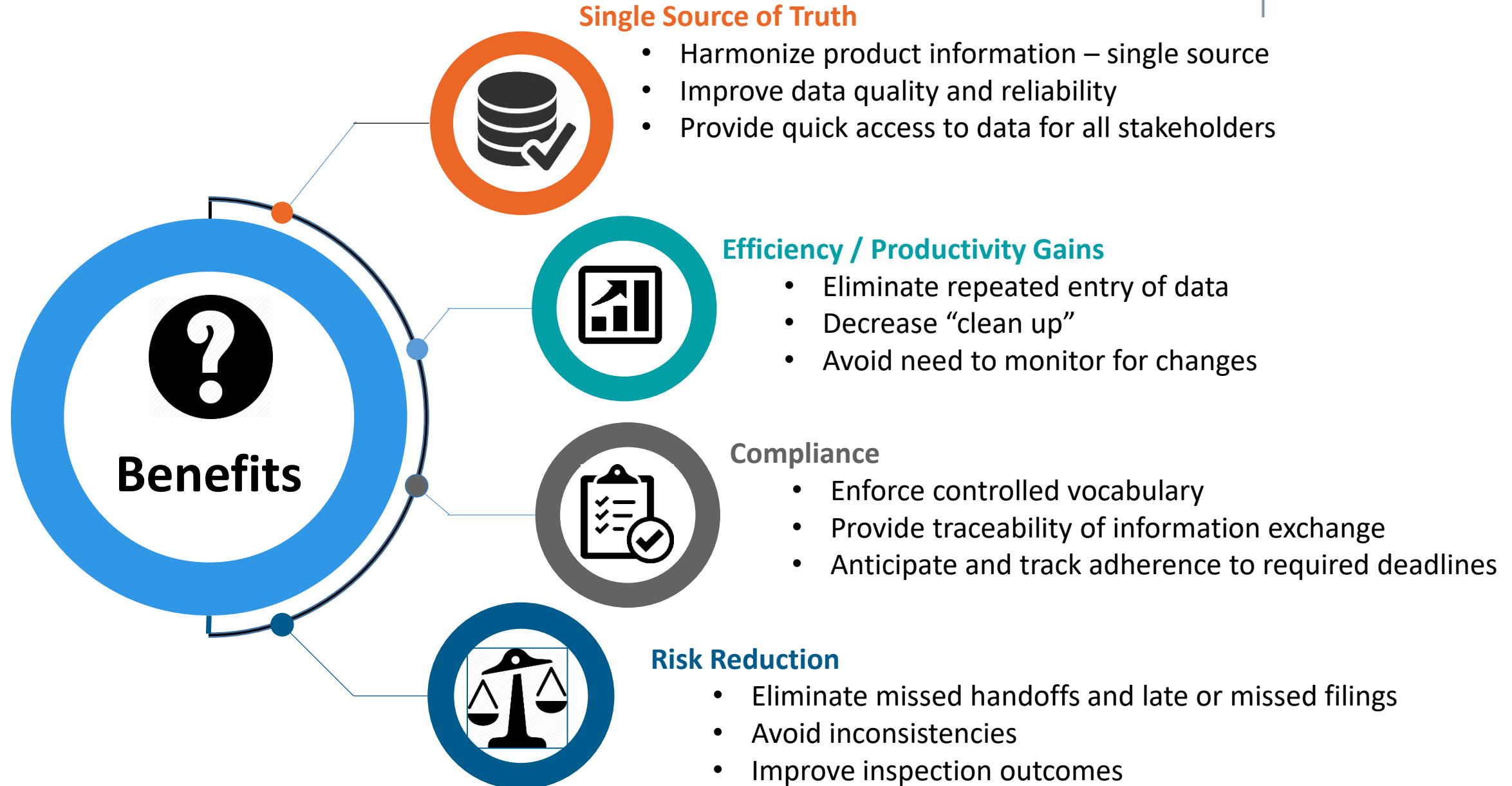
Because each of these components should be communication with 1..n others



Clinical Unification:
Not Just "Buy the Right Software and You Are Done!"
(or "We've Got APIs")



Begin with **Expected Benefits** of Unification



Components of Prioritization Decision



Project Effort

- Is it an IT Project?
- How much work for your team (including validation)?
- How much business process work?
- How much harmonization work?



ROI

- How much will the unification be used?
- How much effort in manual processes?
- How many hours saved? For which resources?
- What can resources do instead?



Risk Avoidance

- Is this a risk area or just a potential efficiency gain?
- Does this integration pertain to compliance issues or audit /inspection findings?
- Could manual processes be improved instead?



Cost

- Software to be purchased or licensed
- Consulting fees
- Internal costs
- Opportunity costs

The Four Elements of Unification

Alerts

Dashboards that show actionable insights; notifications that trigger user actions

Data

Shared data and streamlined implementation of standards



Workflow

Workflows that span traditional “silos”

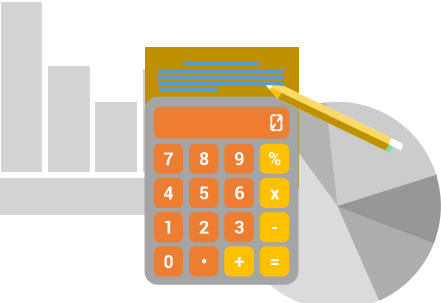
Documents

Common set of documents used by all processes and stakeholders

Unification – Beyond Document Sharing



Unified workflow – statuses, actions and completions in one part of the unified system trigger workflows and escalations across the enterprise

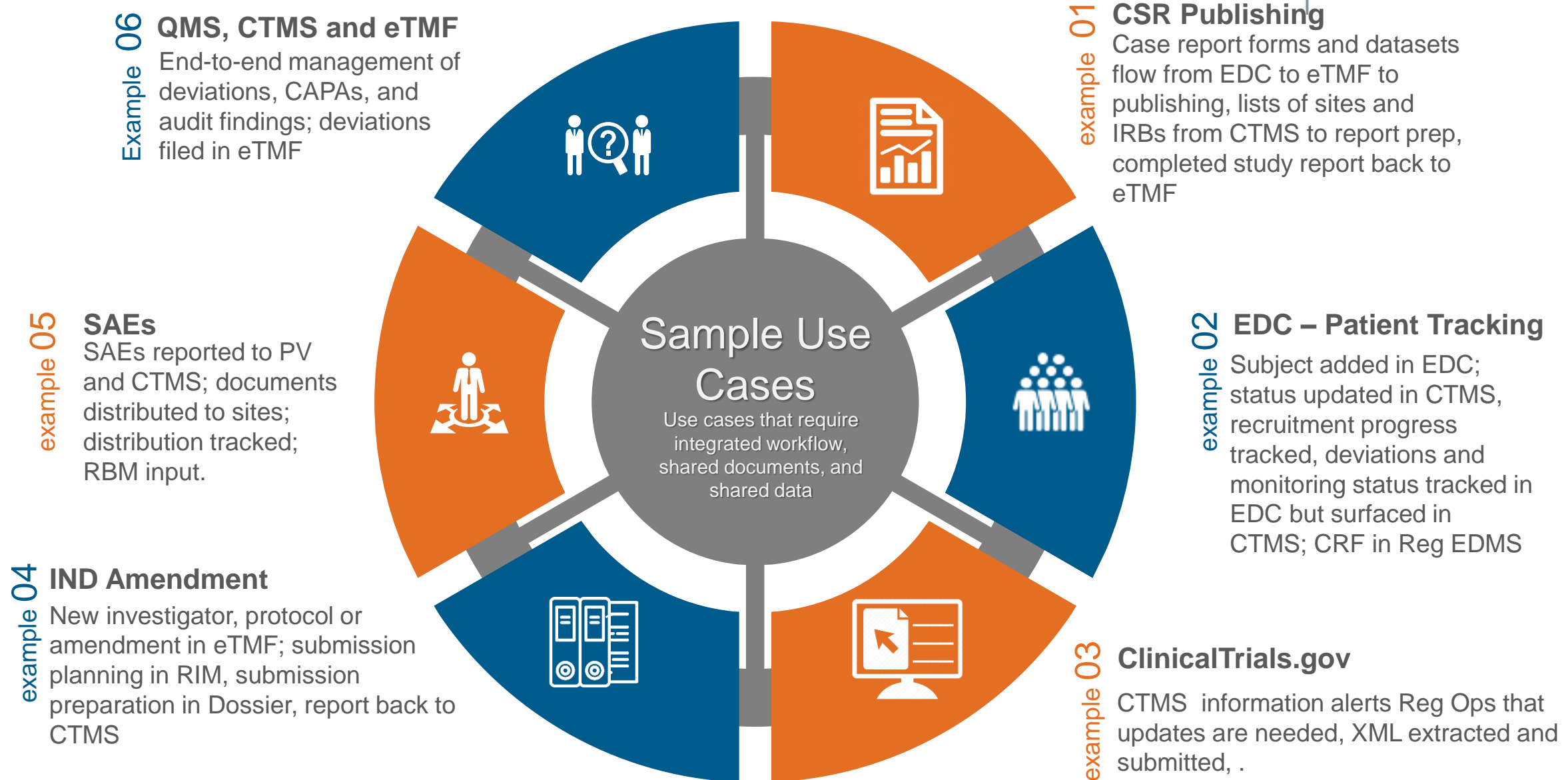


Unified information – all portions of the unified system share master data and documentation, and can access common information on processes and statuses for reports and dashboards



Unified alerts – dashboards and notifications ensure that all users are notified when conditions or events in any part of the system require them to take an action or make a decision

Important Unification Use Cases



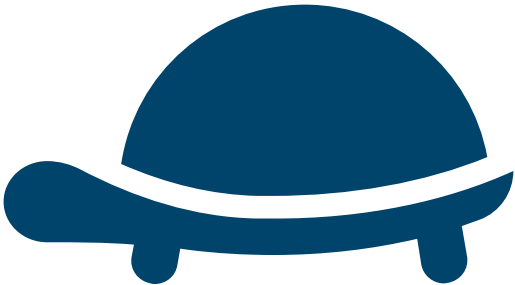
A Sample Prioritization Exercise



Element	Weight	CTMS - CLINICALTRIALS.GOV	CTMS - RIM INTEGRATION
How often would this be used?	5	4: at least monthly	5: dozens of times monthly
What is the project cost (software)?	6	0: \$0	2: \$21K-\$50K
What is the project cost (consulting)?	6	1: < \$20K	3: \$51K-\$75K
What is the project cost (internal)?	4	1: < \$20K	4: \$76K-\$100K
How many staff hours would be saved annually?	8	3: 51-200	5: 501-1000
Can existing manual processes be improved?	2	6: Some improvements possible	6: Some improvements possible
Does lack of unification cause compliance issues? (0 - 9)	10	5	7
Does lack of unification significantly increase risk? (0 - 9)	10	5	7
How long would a unification project take?	4	3: 6-8 weeks	3: 6-8 weeks
How much business process redesign is needed? (0 - 9)	6	2	4
How much harmonization across regions is needed? (0 - 9)	8	0	4
How much alteration of current solutions is needed? (0 - 9)	4	2	4
How much impact does freeing up resources have? (0 - 9)	3	2	4
VALUE OF PROJECT		456	435

Unification: How Do We Get There?

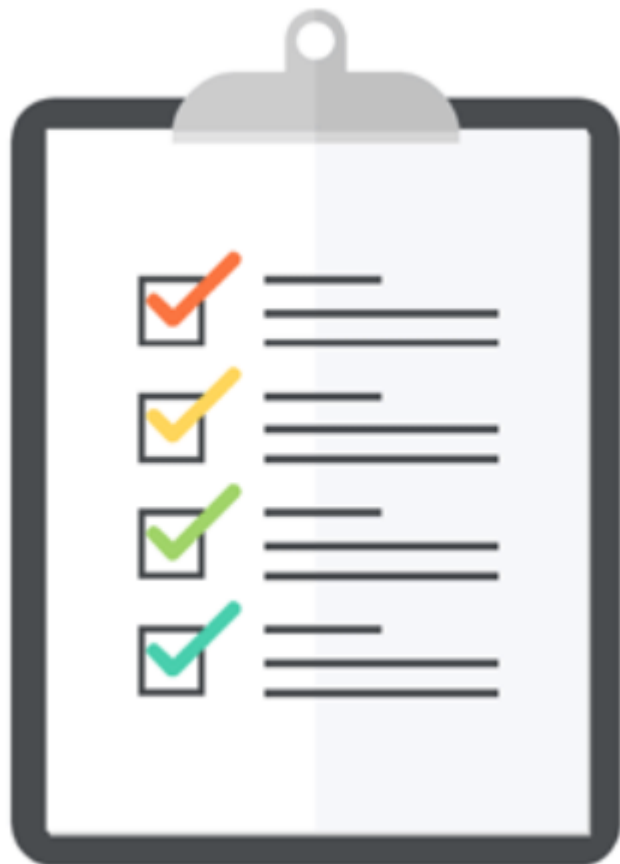
<p>INVEST HEAVILY</p> <p>Provide business justification for making significant investment now.</p>	<p>DELAY OTHER INITIATIVES</p> <p>Prioritize over adding new technology, implementing new features....</p>
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<p>PLAN NOW, DO LATER</p> <p>Concentrate on developing a plan which will be executed in a year or two..</p>	<p>USE EXISTING RESOURCES</p> <p>Make the best possible decisions to make progress using the resources you have now.</p>
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- **Be proactive, not reactive.** Develop a strategic plan for unifying, don't just react to problems as they arise or implement because a vendor offers an integration.
- **Don't be derailed by edge cases.** Interactions that only arise infrequently can still be handled by manual processes.
- **Consider the impact of emerging technology and regulations.** For example, regulations such as XEVMPD may impact the priority of unification in specific areas. Machine learning and AI may also shape direction.
- **Be pragmatic about which legacy systems should be replaced to achieve unification.** As with most projects, a realistic cost/benefit analysis should direct this decision, not just excitement about new technology.

“ An **edge case** is a problem or situation that occurs only at an extreme (maximum or minimum) operating parameter. ”



- 1** Unification can yield significant cost savings, control headcount growth, and reduce risk
- 2** Unifying eClinical systems is still a project requiring time and resources (no matter what the vendor says)
- 3** Articulate the benefits you want to achieve and the relative weight of each benefit
- 4** Ask the hard questions about what vendors offer as unified solutions – still a major project to integrate?
- 5** Keep in mind that true unification goes beyond sharing documents and data to include unified processes

Thank You!



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