Research Quality Initiatives

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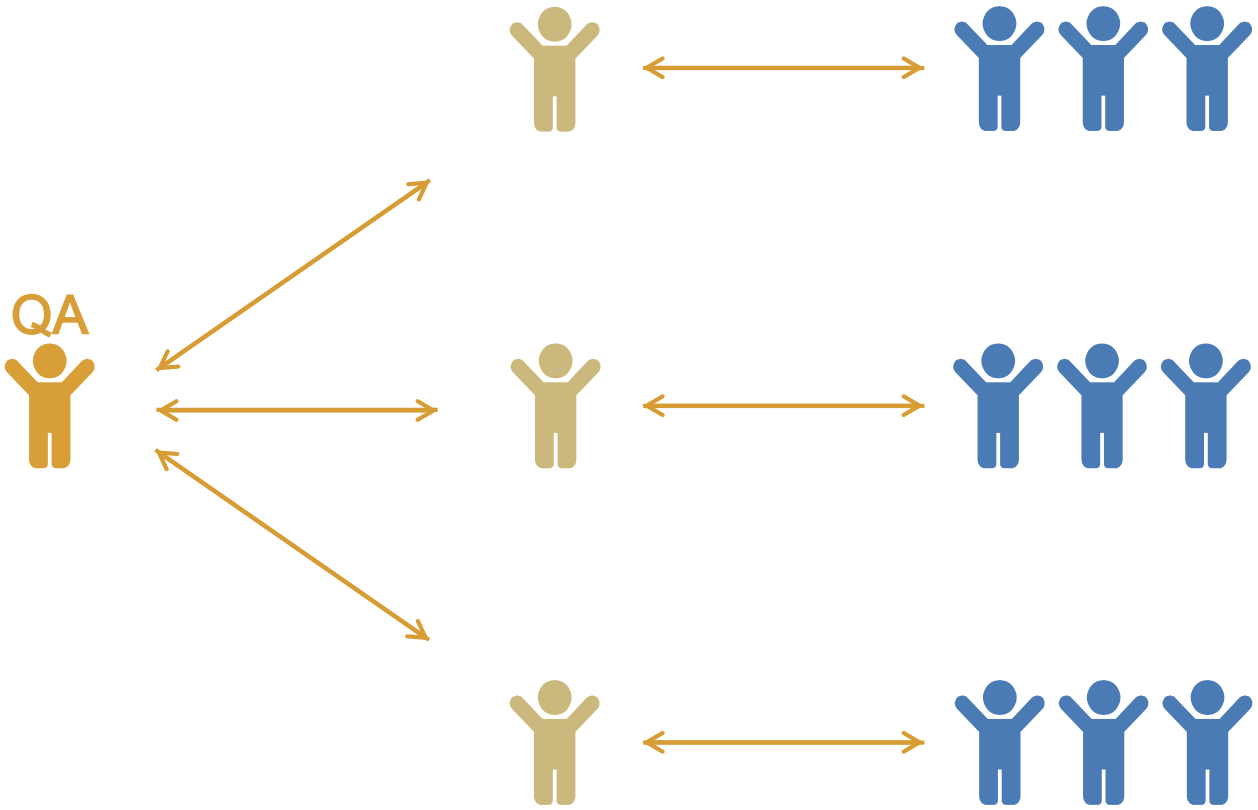
No conflict of interest to declare.

“Quality is everyone’s responsibility.

- W. Edwards Deming

UHN Princess Margaret Cancer Centre

QA Engagement Approach




REACTIVE
PROACTIVE

Quality Initiatives

1. Hands-On Quality
2. Study Tools Working Group
3. Quality Connects

Hands-On Quality (HOQ)

The Why and How

- Quality awareness
- Staff engagement
- Knowledge transfer

- Hands-on approach
- Discussions/networking
- Presenting to home department
- Two-way feedback

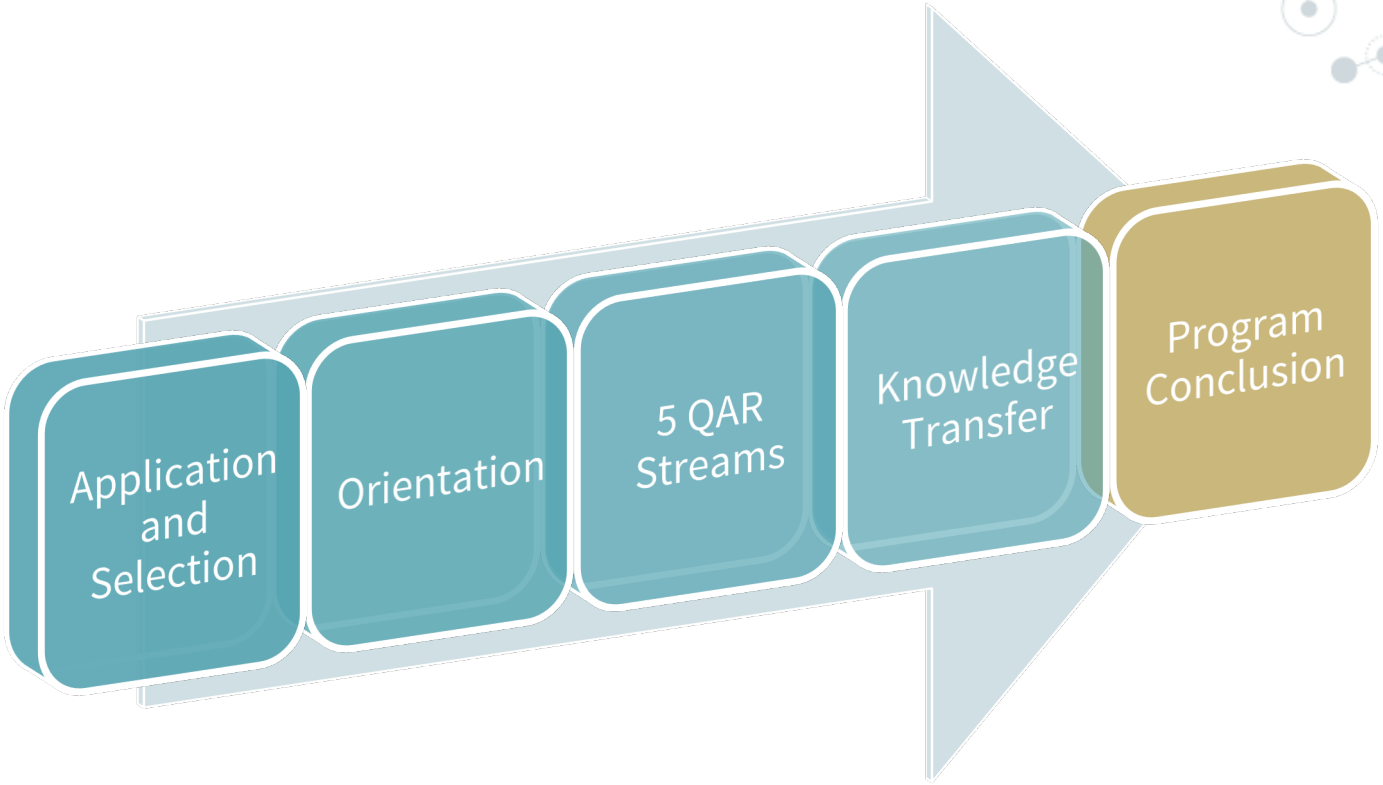
Types of QA Review

Pre-audit Reviews

Process Focused Reviews

Routine QARs

HOQ Components



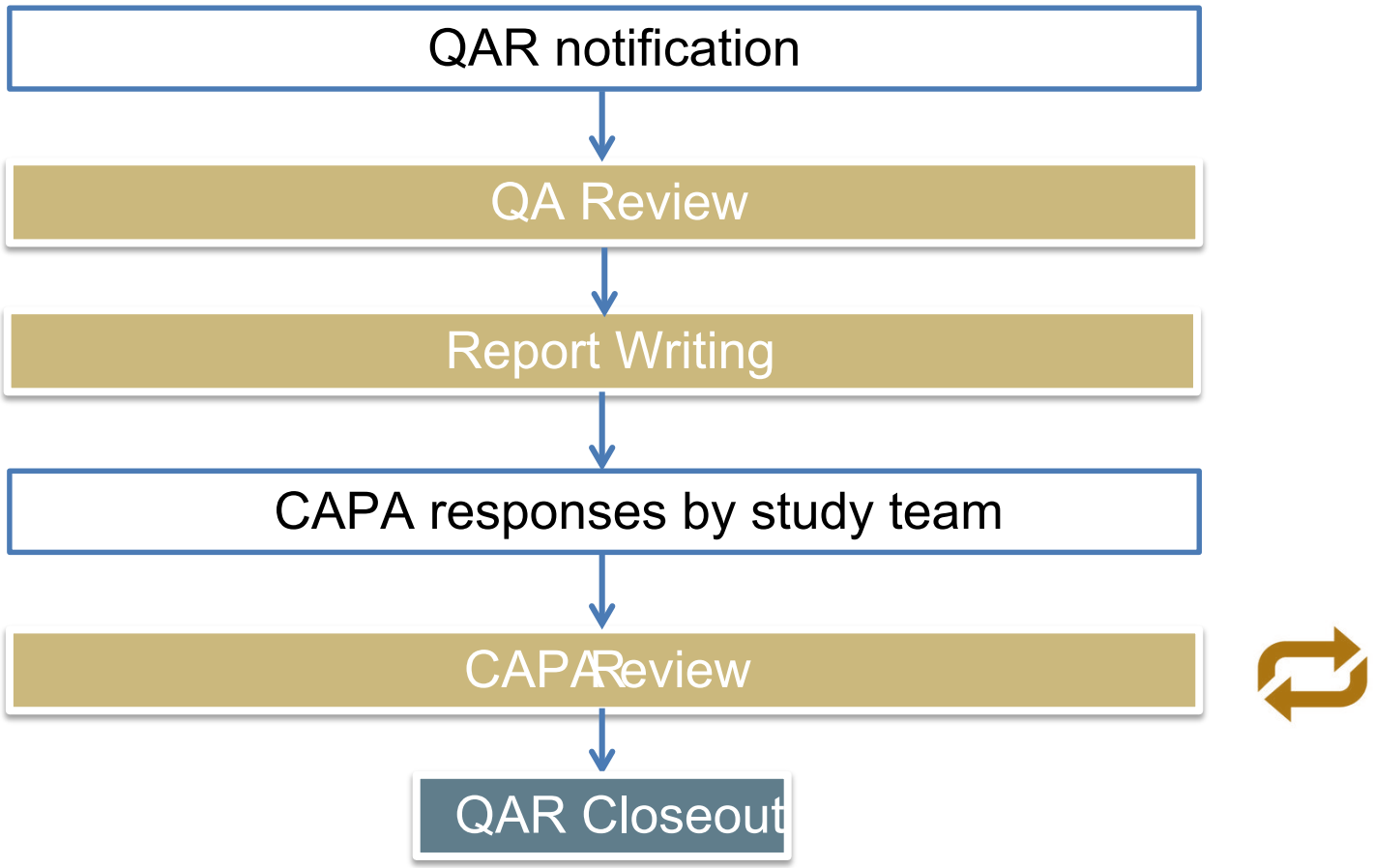
Application and Selection Process

- Gauge interest
- Determine size 10
- Selection criteria
- Application process
- Communications
- Review and selection

Orientation

- 1 hour session for all participants
- Ice breaker
- QA topics covered:
  - Conducting QAR – workflow
  - QAR tools
  - Report writing
  - QA metrics and CAPA
  - HOQ Logistics
- Reading materials

The QAR Process



Types of QA Review

	Feb Stream	Mar Stream	Apr Stream	May Stream	Jun Stream
Feb	QA Review				
Mar	Report Writing	QA Review			
Apr		Report Writing	QA Review		
May	CAPA Review*		Report Writing	QA Review	
Jun		CAPA Review*		Report Writing	QA Review
Jul			CAPA Review*		Report Writing
Aug				CAPA Review*	
Sep					CAPA Review*

* Contingent on when study team returned the responses.

QA Review

- Duration: 1 day
- Prep work:
  - Modify report template
  - Prepare QAR checklists
  - Book room and laptops
  - Circulate protocol
- Intro session at the beginning
  - Basic tips on conducting QAR (e.g. how to prioritize, how to take notes)
  - Reminder of what to expect throughout the day (i.e. AM/PM split, time management)
- Available throughout day to help pace the participants and answer questions

Report Writing

- Duration: 2 hours
- Review basics of writing QAobservations:
  - Descriptive and specific
    - Dates, location of file, specific statements
  - Third person
  - Avoid blame and assumption
  - Recommendation for each finding
  - Note areas of good practice
- Practice writing select findings based on notes from the 1-day QAR

CAPA Review

- Duration: 2 hours
- Pre-selected CAPAs for review:
  - Good and bad CAPAs
  - Atypical findings and discussion generators
- Review what to look for in a CAPA:
  - Detailed
  - Does it address the **root cause**?
  - Is it feasible?
- Discuss elements of good vs. bad CAPA
- Write further comments to select CAPAs

Knowledge Transfer

- 20-30 min presentation to home department/team on QArelated learning.
- Focus: sharing practical knowledge.
- Goal:
  - Increase quality-related awareness
  - Increase transparency on QAoperations
- Opportunity for Q&Aand reciprocal feedback to QA.

Program Conclusion

- Don’t forget to celebrate and reflect

Survey Highlights

- Invaluable hands-on experience
- Opportunity for perspective taking
- Interesting discussions with members of other departments / teams
- “Incidental” self-training (“I need to go back and check my own trial.”)
- Getting in the mindset of **quality** – think like an auditor
- Passing on the information to other team members

Challenges

- Catering to the interest of individuals from various backgrounds and experiences – no one size fits all
- Time commitment to a project aside from daily responsibilities
- Booking sessions: coordinating with 11 different schedules
- Gaps between sessions – how to keep participants engaged

The Future of HOQ

- On-Demand format
- More dedicated QA manpower
- Not changing: main framework of the program
- Addition of a QAR Planning session:
  - Review protocol/amendments
  - Create study patient specific checklist based on the protocol
  - Conduct the patient selection process
- Monthly touch-base sessions to keep participants engaged
- Re-design surveys to collect feedback

Study Tools Working Group (STWG)

What are Study Tools?

- Documenting study specific information that cannot be found elsewhere
- Allow for trending via a tracking mechanism
- Keeping the study team on track/compliant
- Patient specific (source document) or non-patient specific (regulatory document)

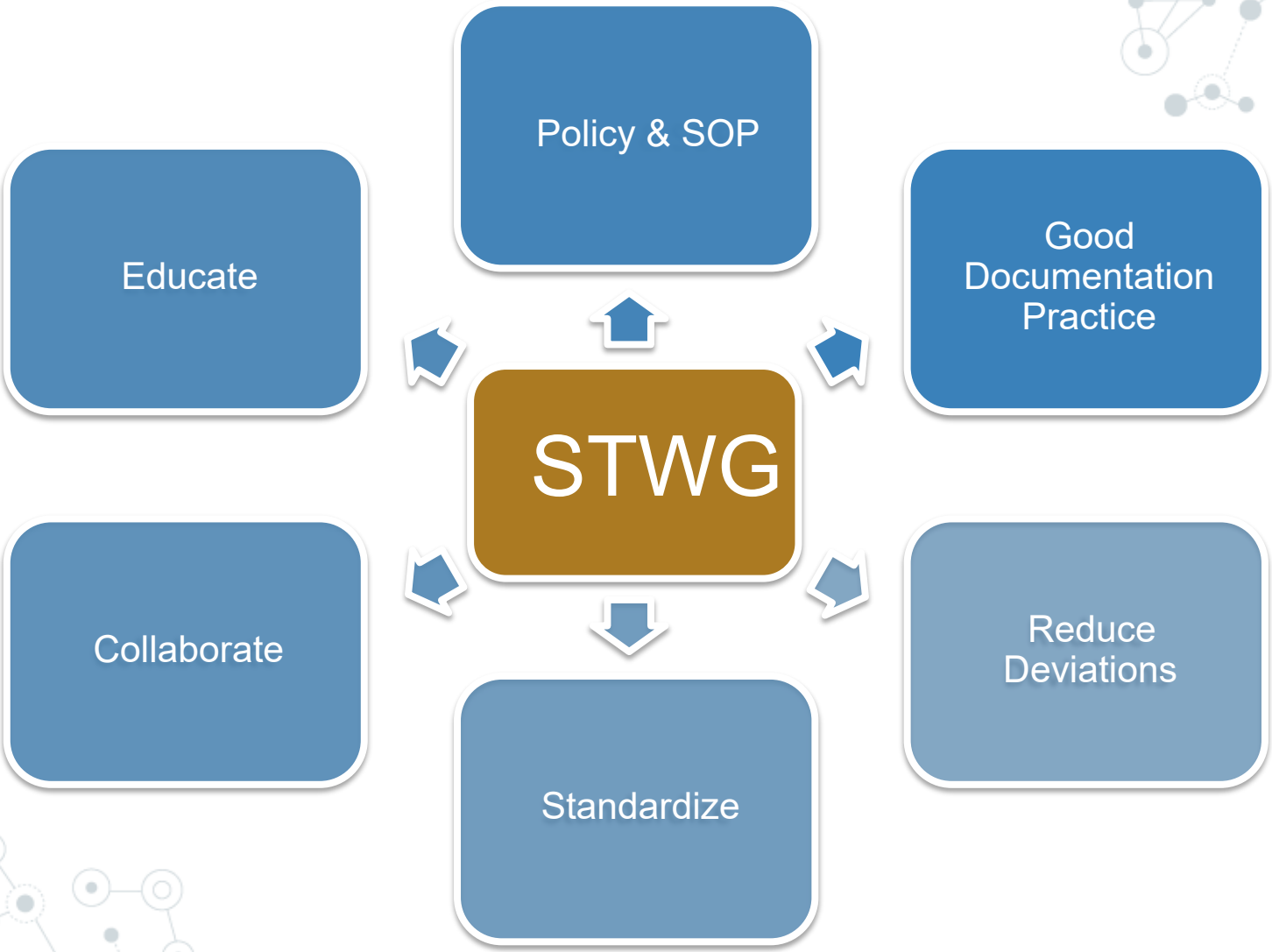
- Goals:
  - Reduce errors or non-compliance
  - Standardization and increased consistency

Types of Study Tools

Standard Templates

Study Specific

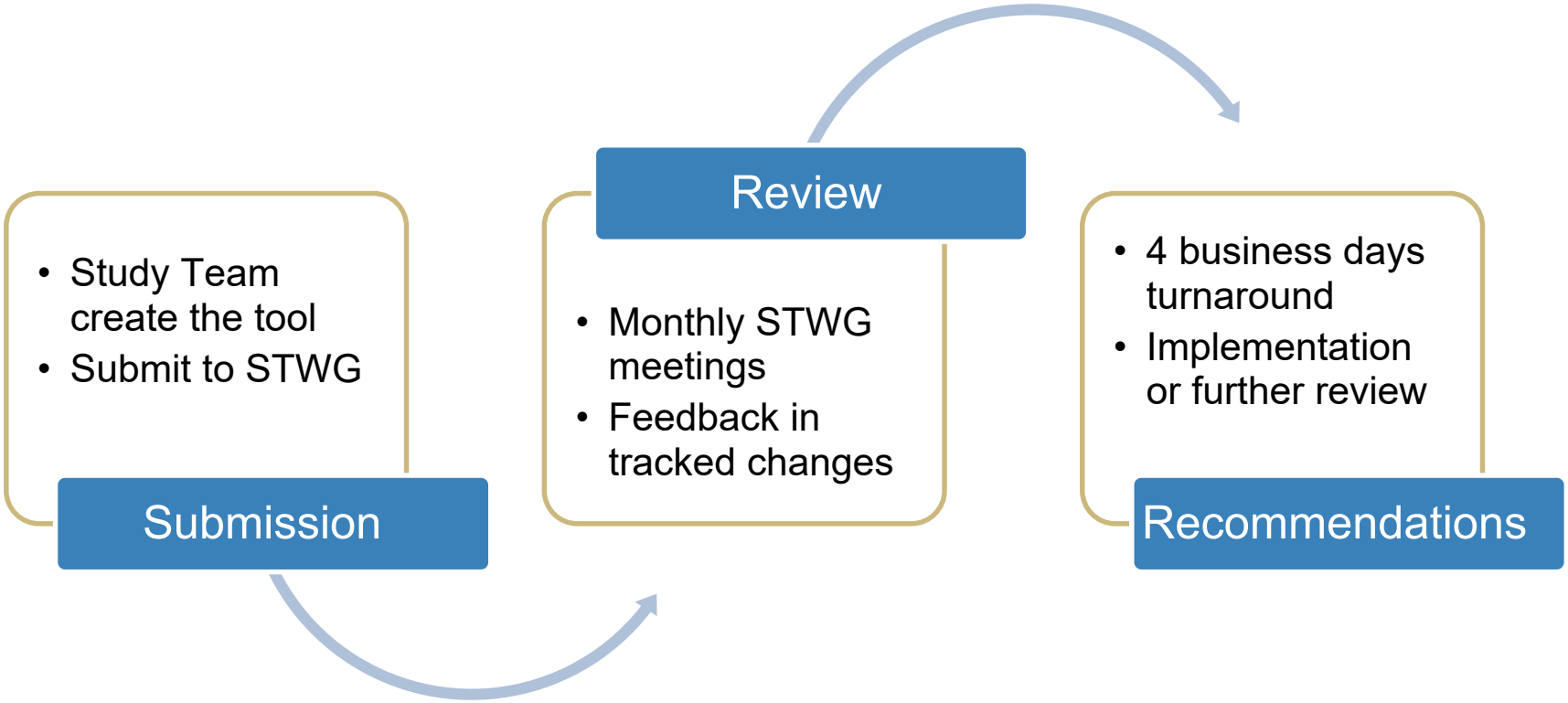
A STWG Was Born



STWG Scope

In Scope?	Yes	No
Review of study-specific tools created by study team	✓	
Creation or modification of standardized templates	✓	
Review of non-routine modifications to standardized templates	✓	
Review of routine modifications to standardized templates		✓
Creating study specific tools		✓
Revising study specific tools		✓
Review of tools against the protocol		✓
Review of study checklists		✓

STWG Review Process



Study Tool Submission

- Prior to study activation
- Work as a team (!!)
- Aim for STWG meeting dates
- Designated e-mail box, subject line
- Format: MS Word, tracked changes
- Provide background

Modifying a Standard Template

- Read the instructions
- Ensure those fields not required by the protocol are removed
- Add additional protocol required fields, if applicable
- Add signature/initials and date fields if tool is to be completed by multiple individuals
- Version Control
- Submit to STWG for review, if changes are significant

Creating a Study Specific Tool

- **First check if a standardized template exists**
- Create only fields that are required by the protocol
- Do not collect information that are found elsewhere(avoid “double documentation ”)
- ALCOÆC principles
- Workas ateam (!!)
- Submit to STWG for review

Study Tools Management

- Version control (template version vs. study modification version)
- Instruction page for standard tools
- Be mindful of amendment changes
- Communication to the study team
- Central repository of standard tools

Using Study Tools

- Is it the most current version?
- Identifiers
- No blank fields
- ALCOA-C principles
- Pagination
- No rough notes in the margins

Quality Connects

Quarterly Quality Connect

- Wider audience – anyone welcome
- Real life examples from QARs; good vs. bad CAPAs
- Trends from audits and inspections
- QAspecific highlights, updates, reminders

Quality Lead Connect

- Smaller Group
- Sharing of QA methodology
- Regular review of QA metrics and trends
- Greater focus on specific department processes and gaps
- More solution driven

Take Home Messages

1. Think creatively
2. Engage the community

Thanks!

Any questions?

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