No conflict of interest to declare.
“Quality is everyone’s responsibility.”

- W. Edwards Deming
QA Engagement Approach
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
Orientation
5 QAR Streams
Knowledge Transfer
Program Conclusion
Application and Selection Process

- Gauge interest
- Determine size
- 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
  - QAmetrics and CAPA
  - HOQ Logistics
- Reading materials
The QAR Process

1. QAR notification
2. QA Review
3. Report Writing
4. CAPA responses by study team
5. CAPA Review
6. QAR Closeout
# Types of QA Review

<table>
<thead>
<tr>
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<th>Feb Stream</th>
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<th>May Stream</th>
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* Contingent on when study team returned 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 QA observations:
- 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 QA-related learning.
- Focus: sharing practical knowledge.
- Goal:
  - Increase quality-related awareness
  - Increase transparency on QA operations
- Opportunity for Q&A and 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

- Policy & SOP
- Good Documentation Practice
- Reduce Deviations
- Standardize
- Collaborate
- Educate
## STWG Scope

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<td>Creation or modification of standardized templates</td>
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STWG Review Process

**Submission**
- Study Team create the tool
- Submit to STWG

**Review**
- Monthly STWG meetings
- Feedback in tracked changes

**Recommendations**
- 4 business days turnaround
- Implementation or further review
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”)
- ALCOAC principles
- Work as a team (!!!)
- 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
- QA specific 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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