



Regulatory Submissions
and Advisory Committee Meetings

Pulling it All Together



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Topics



- **Introductions**
- **Final Stage Submission Activities**
- **Final Stage Advisory Committee Meeting Activities**
- **Parallels in the Process**
- **Q&A**





- **Octagon Research Solutions, Inc. is a development partnering organization that offers regulatory, clinical, process and IT solutions to the life sciences industry**
- **The Octagon Advantage:**
 - Deep Domain Knowledge
 - Cross-functional eSub Expertise
 - A Holistic Process Approach
 - Creative Use of Technology



- **Presentation Strategies Inc. is a premier interactive production company serving the pharmaceutical industry**
- **Single Source for mission critical media solutions:**
 - Strategic Audiovisual Services
 - Multimedia development and deployment
 - Video production
 - Digital printing
 - **Regulatory presentation management**

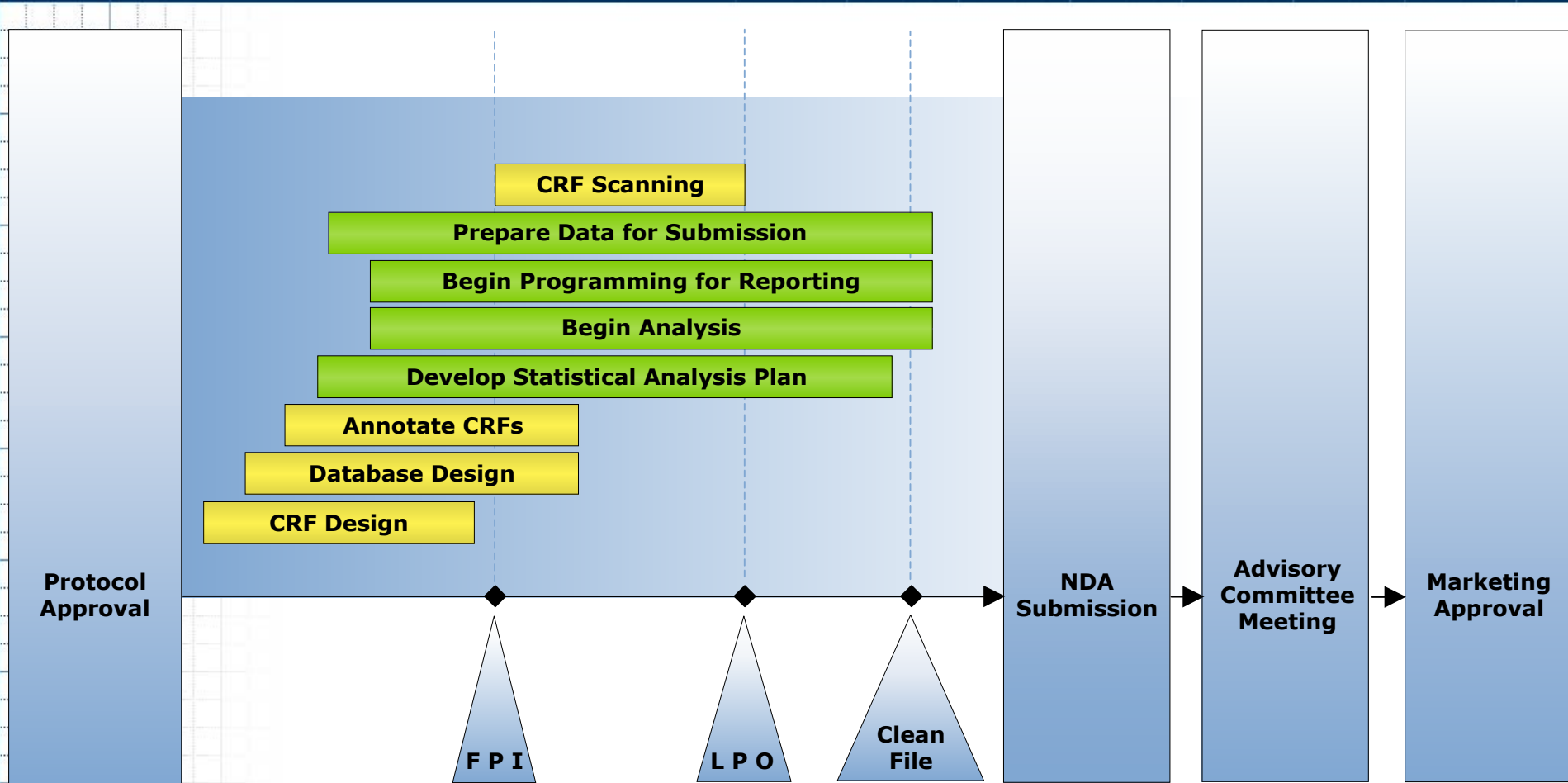
Polling Question



How many attendees have experienced the chaos that occurs the last week(s) before a submission?



The Big Picture



Pulling it all Together: Final Stage Submission Activities



- **Agency Communications**
- **Organizational Readiness**
- **Logistics – Internal/External**
- **Unexpected Challenges**
- **Next Activities**
- **Debrief Meeting**

Pulling it all Together: Agency Communications



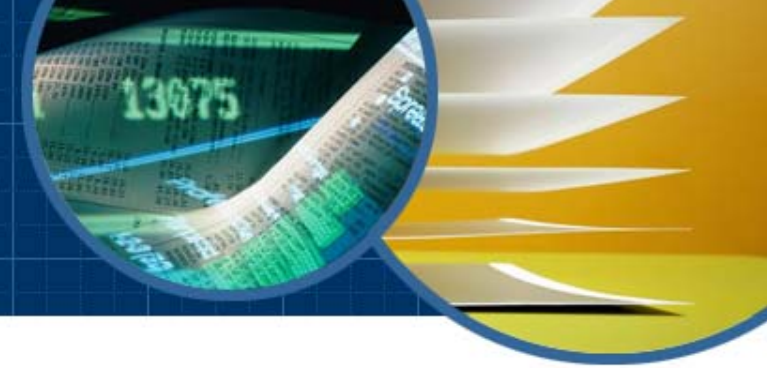
- **Review agency agreements to ensure compliance**
- **Continuous dialog is required**
- **Minimize risk – ask the question now**
 - **Agency is working through same learning curve**
 - **Document answers to expand organizational knowledge**

Pulling it all Together: Organizational Readiness



- **Lock down content – FINAL is final!**
- **Hope is not a strategy!!**
- **Walk through “what if” scenarios to determine impact on deadlines**
 - **Document dependencies**
 - **Executive approvals**
 - **Overlapping of stacked workflows**
 - **Inundate skilled resources (QA)**
- **Operational issues may escalate to strategic levels very quickly in the final days of the project**

Pulling it all Together: Logistics



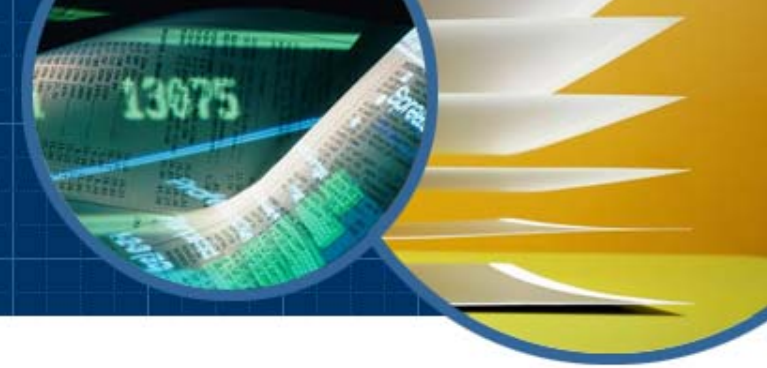
- **Submissions Coordinator is Key**
 - Logistics include internal and external factors
 - Communications
- **Secure final approvals prior to final burn**
- **Don't sacrifice final stage QA to meet time constraints**
 - Burn CDs, load and QA final output (replicate agency procedures)
 - Make all copies from same source
 - Control access to final deliverable
- **Arrange delivery**
 - Confirm document room schedule
 - Request confirmation call from delivery service

Pulling it all Together: Unexpected Challenges



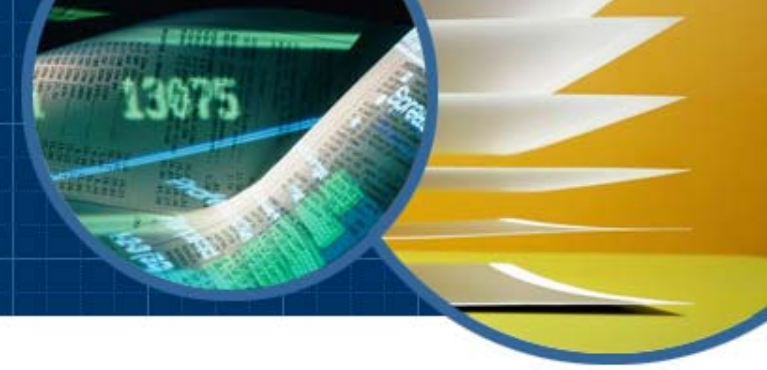
- **Last minute changes often result in “process exceptions” that must be managed**
- **Global understanding of requirements (at all levels) is essential**
- **Enabling technology is only as good as the process**
- **Transitioning to new eSub processes is a continuous investment**
- **Murphy’s Law**

Pulling it all Together: Next Activities



- **Internal distribution: location, navigation of completed application**
- **Ad hoc requests – CRFs, Questions**
- **120 Day Safety Update (Item 9)**
- **Advisory Committee Briefing Document**
 - **Not eDoc – can be published from eNDA/eCTD content**
 - **Available via Internet**
- **Labeling negotiations**

Debrief Meeting



- **Timing: shortly after submission**
- **Attendance: Mandatory all contributors to process (include support organizations such as IT, Administrative personnel, etc.)**
 - **Make it worth their time**
 - **Agree to action plan (report) upfront**
 - **Set the tone**
- **Document and escalate cross-functional issues**
- **Compile relevant metrics (good and bad)**
- **Celebrate and Congratulate!**

Polling Question

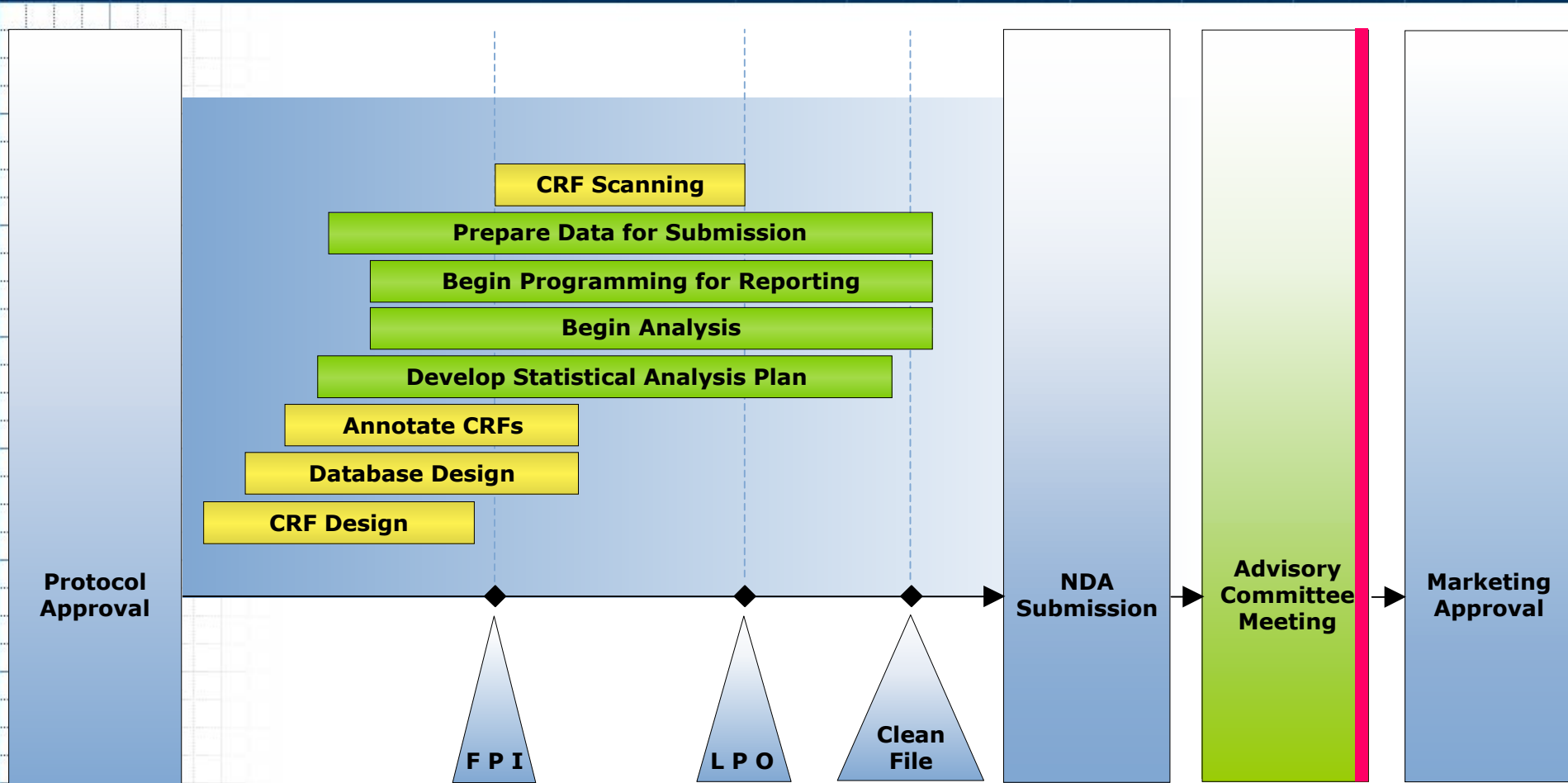


On average, how many backup visuals are shown during Q&A?

- 1) 3**
- 2) 5**
- 3) 13**
- 4) 18**
- 5) 26**



The Big Picture



Pulling It All Together in Washington DC



- **Onsite Requirements**
- **The Day Before**
- **The Room Layout**
- **The Presentation**
- **Q & A**



Pulling It All Together: *Onsite Requirements*



Take Care of Your Team

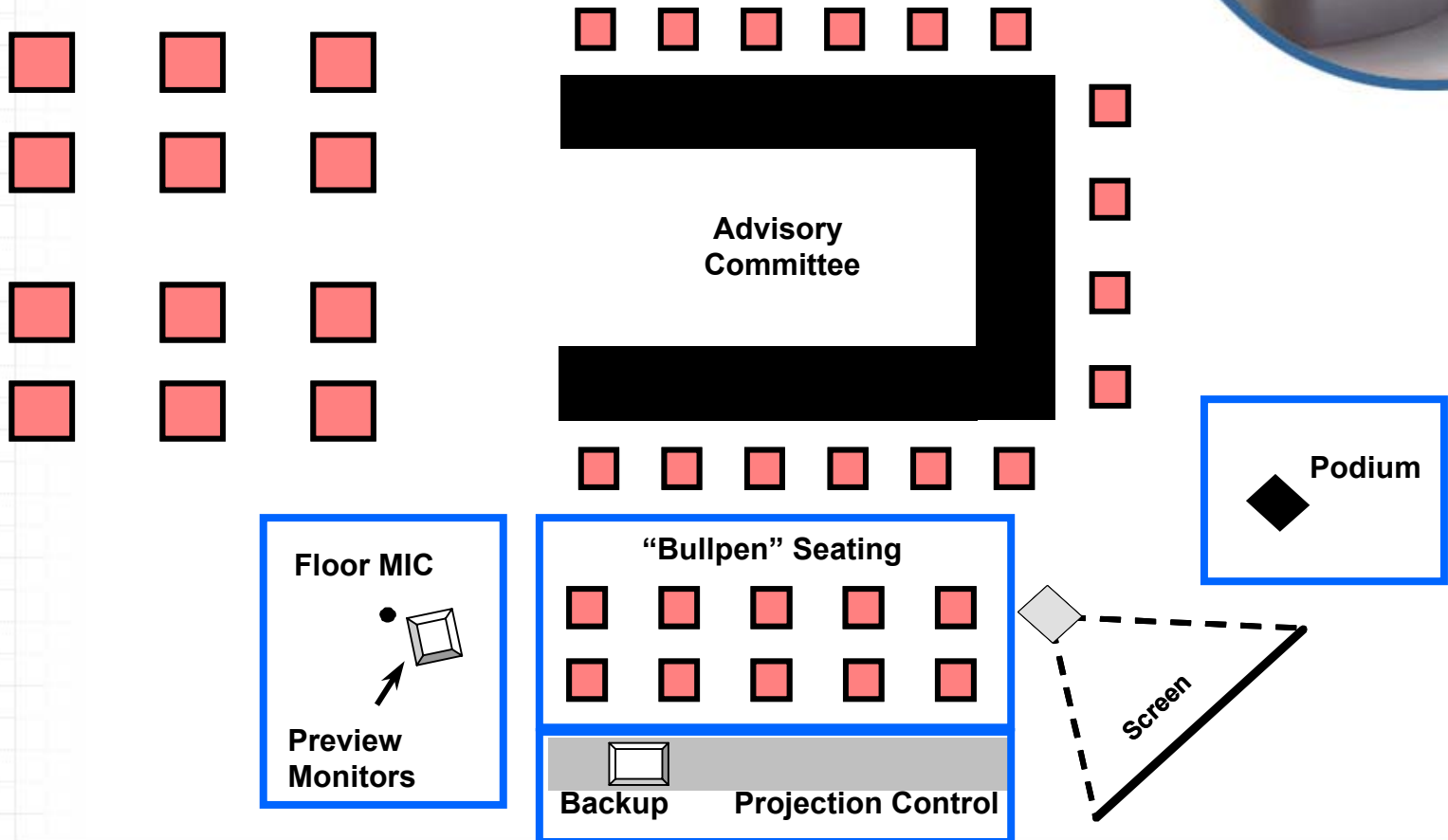
- **Make arrangements early!**
- **Choose a comfortable hotel**
- **Adequate meeting room for final rehearsal**
- **Plan for security**
 - **All workrooms lock**
 - **Security personnel**
 - **Shredders**
- **Set a manageable schedule and keep to it**

Pulling It All Together: *The Day Before*



- **Final formal mock rehearsal**
 - **Confidence**
- **Highly polished, scripted core presentation**
- **Bullpen ready to provide direct responses to Committee questions**
 - **Confident in use of all retrieval systems**
- **Finish rehearsal and work by 5:00 PM**
- **Walk-through of AdComm meeting room**
- **A/V setup**
- **Printed materials for Committee members**

Pulling It All Together: *The Room Layout*



Pulling It All Together: *The Presentation*



- **Finalize A/V setup – 6:00 am**
- **Handouts to Executive Secretary**
- **Presenters' focus on Committee**
 - **Scripted advance of visuals**
 - **Presentation designed to highlight without laser pointer**
- **Smooth transition between speakers**

Pulling It All Together: Q & A



- **Entire team portrays calm, professional demeanor**
- **Direct answer method**
- **Only use visual support if absolutely needed**
- **If needed, access visuals in 5 – 10 seconds**
- **Clear communication for visual projection**
- **Effective use of preview monitors**
- **Tracking backup visual usage**

Pulling It All Together: *The Celebration!*



There are two types of celebrations:

- **The team did a great job – but did not get all of the desired result**
- **The team did a great job and got the desired result**

Pulling It All Together: Debrief Meeting



- **Timing: shortly after submission**
- **Attendance: Mandatory all contributors to process (include support organizations such as IT, Administrative personnel, etc.)**
 - **Make it worth their time**
 - **Agree to action plan (report) upfront**
 - **Set the tone**
- **Document and escalate cross-functional issues**
- **Compile relevant metrics (good and bad)**

Parallels in the Process



- **Complex team dynamics impact success of project**
 - **Leadership roles are key**
- **Continuous visibility into developing process is essential**
- **Flexible and controlled planning prevents last minute chaos**
- **Debrief will always reveal cross-functional issues or opportunities for efficiency and growth**

Top 5 Recommendations



- **Work toward organizational understanding**
- **Engage and educate early**
- **Focus on your communication strategy**
 - **Internal**
 - **Agency**
 - **Committee**
- **Identify and leverage specific expertise required for success**
- **Don't forget to acknowledge your successes!**



Question and Answer Session

Presenter Contact Information



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Upcoming Events



Look for us at the DIA 41st Annual Meeting in Washington, D.C.

June 26-30, 2005

Session Title: "*Product Team Transitions: Success Criteria Throughout the Product Lifecycle*"

Date and Time: TBD

Octagon Research Solutions Booth # 1809