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# Ensuring Data Quality and Productivity when Implementing a Rescue Study in EDC: Lessons Learned

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The presenters have disclosed that they have no proprietary or financial interests in the topics covered in this presentation.



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# Ensuring Data Quality and Productivity when Implementing a Rescue Study in EDC: Lessons Learned

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# Our Rescue at a Glance



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- Transitioned 9 federal studies
- Paper to EDC
- Complicated study design/indications
- Multiple CRF versions

# Our Implementation



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- How we prepared within our organization
- What we needed from the client
- What was available from the previous vendor

# Lessons Learned

## Assemble the Team

## Assess Resourcing



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- Create specialized work groups
- Create a “triage” specialist

# Lessons Learned Assess Client Needs



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## Negotiate

- Balance the timelines with true study needs
- Provide realistic expectations about timing
- Establish changes the client wants up front

# Lessons Learned

## Assess Client Needs



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## Educate

- Discuss process changes for sites and the client
- Review requested changes against contract/budget

# Lessons Learned Obtain Information from the Previous Vendor



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## Vendor Specific

- Format of data capture and software used
- Vendor processes
- Timing of transition for each study

# Lessons Learned Obtain Information from the Previous Vendor



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## Study Specific

- Scope
- Data status
- Timelines
- Study specific decisions and documentation

# A Second Rescue at a Glance



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- Transitioned 10 federal studies from same vendor
- EDC to EDC
- Relatively simple study design
- Multiple CRF versions

# A Second Rescue Lessons Applied



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- Provided realistic expectations based on experience not assumptions
- Negotiated changes in reporting timelines
- Processed changes

# A Second Rescue

## More Lessons to Learn



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### New Issues

- Data capture system anomalies
- Not all data was transferred
- Data mapping issues on the vendor side
- Test data did not account for possible data scenarios



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# Discussion:

What questions can we answer?

Do you have a war story to share?

# Feedback Assessment



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- Please Complete Evaluation!!

# Thank You!



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