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Documenting Training Using REDCap

Carol Claro

Robin E. Ryan

Keith August

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DOCUMENTING TRAINING USING REDCAP

Children's Mercy Hospital – Section of Oncology

Carol Claro, Robin Ryan, MPH, Keith August, MD

BACKGROUND

ICH Guidelines for Good Clinical Practice (GCP) states, "Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s)." Systemizing and documenting staff training for multi-disciplinary trials is challenging. Prior to 2018, documentation of training at Children's Mercy was not captured in a systematic manner. The COG team wanted to identify a platform for distributing and tracking completion of training materials for study team members. REDCap is a secure web application that can be used to build and manage online surveys. The purpose of this effort was to determine if REDCap could effectively document training.

REDCAP WORKFLOW

New Protocol/Amended Protocol

All new protocols have training initialed as part of start-up. Amendment training is determined case by case based on content

RC (Regulatory Coordinator) creates REDCap survey

See Figure 2 for an example of the ANBL1531 initial training survey

Distribution of survey determined by PI and study staff

PI alerts any delinquent team members post-deadline

Repercussions include the removal of team member(s) from study

REDCAP BENEFITS

REDCap provides:

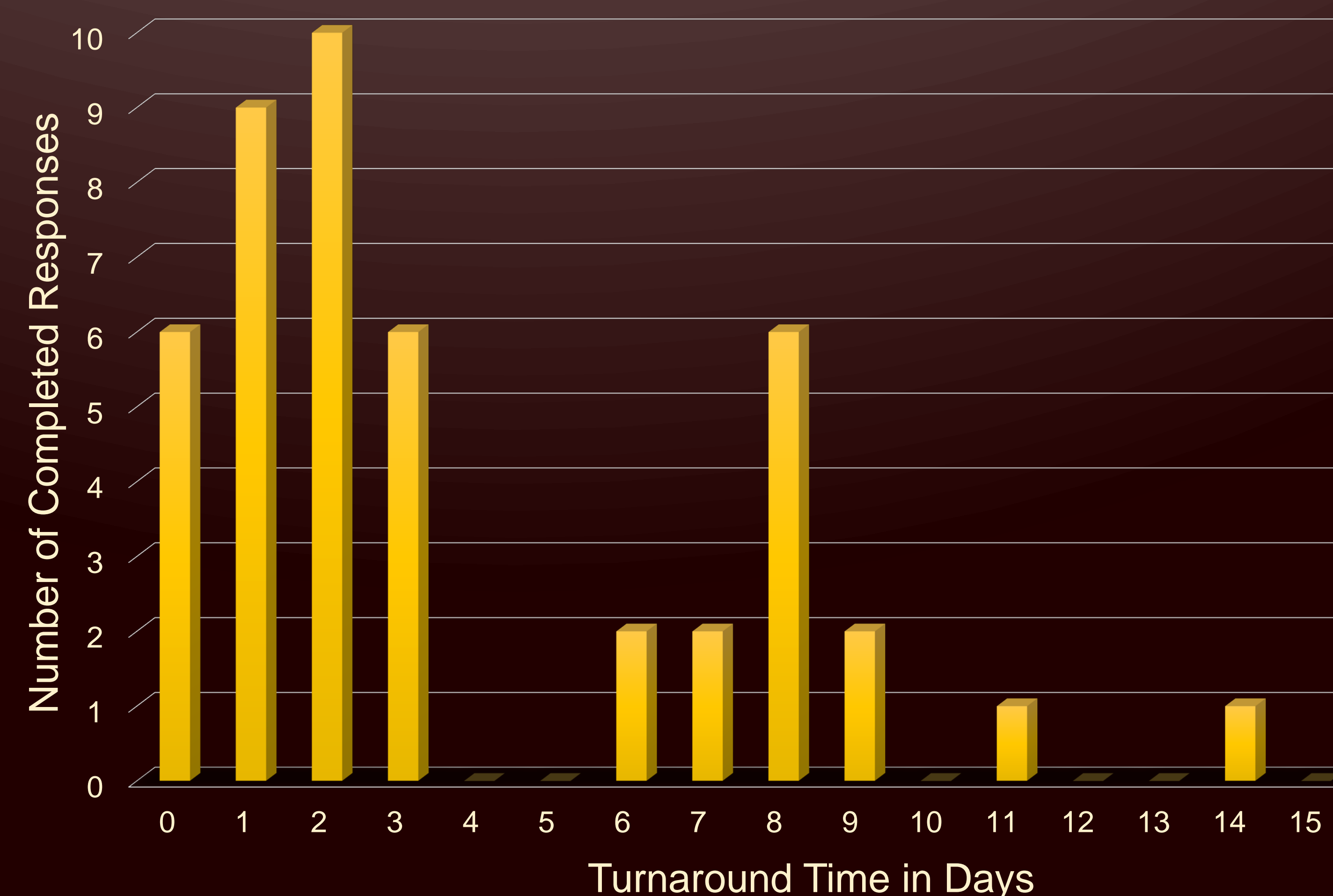
- PI and RC a tool to view completion (Figure 1)
- Automatic email reminders to any delinquent team members
- Submission of any questions or comments
- Replicable system
- Report/training log. The report generates the following filterable fields:

1. Timestamp
2. Attestation
3. Questions/Comments
4. Email signature
5. Date completed

CONCLUSION

Attributes for good documentation as described by the US-FDA are attributable, legible, contemporaneous, original and accurate (Bargaje, 2011). REDCap meets all these attributes and also creates an audit trail of documentation reflecting compliance with GCP. REDCap has become the main tool used for providing and documenting training at the Children's Mercy Hospital – Oncology Division as this effort has been very effective and user-friendly.

Turnaround Time for ANBL1531 Protocol Training



Email	Record	Participant Identifier	Responded?	Invitation Scheduled?	Invitation Sent?	Link	Survey Access Code and QR Code
[redacted]@cmh.edu		Disabled	✓	-			
[redacted]@cmh.edu		Disabled	✓	-			
[redacted]@cmh.edu		Disabled	✓	-			
[redacted]@cmh.edu		Disabled	✓	-			
[redacted]@cmh.edu		Disabled	✓	-			
[redacted]@cmh.edu		Disabled	✓	-			
[redacted]@cmh.edu		Disabled	✓	-			
[redacted]@cmh.edu		Disabled	✓	-			
[redacted]@cmh.edu		Disabled	✓	-			
[redacted]@cmh.edu		Disabled	✓	-			
[redacted]@cmh.edu		Disabled	✓	-			

Figure 1

Figure 2

REFERENCES

- Bargaje, C. (2011). Good documentation practice in clinical research. *Perspectives in Clinical Research*, 2(2), 59–63. <http://doi.org/10.4103/2229-3485.80368>
- International Conference on Harmonisation, Guideline for Good Clinical Practice. Retrieved July 23, 2018, from http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2_Step_4_2016_1109.pdf
- REDCap (Research Electronic Data Capture), Vanderbilt University, <https://www.project-redcap.org/>.