Editorial

The journey to a paperless clinical research unit

Nagham Sheblaq*, Mohammad Al-Kaiyat, Ahmad Al-Qudimat, Abdulrahman Jazieh

Department of Oncology, National Guard Health Affairs, Riyadh, Saudi Arabia

*Correspondence:
Dr. Nagham Sheblaq,
E-mail: naghamramzi1@gmail.com

Healthcare industry started using electronic health records (EHR) and turning into paperless hospitals.[1] This paperless environment has many benefits include enhancement of patient safety and error reduction.[2] Clinical research has evolved significantly over the years and resulted in saving the lives of millions of people and alleviate the suffering of more.[2] Paperwork and proper documentation and storage of documents are essentials aspects when conducting clinical research. Clinical research unit (CRU) is dedicated to assist the principal investigator (PI) in proper coordination, statistical, epidemiological, logistical and methodological supports for any clinical research project in high quality, professional manner and in compliance with the local / global ethical and regulatory standards.[1]

CRU plays a vital role in any research based institution/ agency. It's the essential link between all research parties inside and outside institution such as research subject, investigator, sponsor, contract research organization, regulatory bodies and Institutional Review Boards (IRB). Establishing a successful CRU requires certain expectations such as

1. Defining all process in place as standard operating procedures (SOPs),

2. Selecting and delegating specific duties and responsibilities to qualified trained people,

3. Ongoing training and sharing study information to the whole study team member,

4. Maintaining high quality and secure data,

5. Building a clear communication process between all parties.[3]

In addition to the previously mentioned points, in order to establish a paperless CRU, it requires high awareness of the new technological advances and being able to utilize it efficiently and effectively to improve the clinical research culture and management process.

CRU setting

Our CRU is located in Oncology department at Ministry of National Guard Health Affairs, Kingdom of Saudi Arabia-Riyadh. Our mission is to provide support and facilitate research work for oncology health care providers at different levels of their projects' design, implementation, data management and statistical analysis in order to bring innovative research ideas and projects that are relevant to our population to help our patients and contribute to the advancement of science. Our CRU provides services and support for the various type of study initiators such as investigator initiated trials, sponsor initiated trial and collaborative group trials. The types of studies conducted in our CRU include phase II, III, IV clinical trials, cross-sectional, retrospective, case series studies and quality projects.

In this paper, we describe the transformational process from paper to paperless unit which required major changes to the current practice, and discussing all challenges encountered and advantages added during this journey.

Journey description

We worked on the improvement of nine major elements in our CRU, we will describe the paper (P) versus the electronic (paperless) (E) practice for each element.

Study submission

P: In our hospital, it was required to submit whole study package which is not limited to (study protocol, Investigator's brochure, case report form, bilingual Informed consent forms, etc...) through an official memorandum. We were required to make three copies, one goes to research office, another to the Institutional Review Board and the last one for study record archiving.

E: A friendly use e-submission system was provided from our hospital including all elements for the study protocol as per local/GCP standards, each oncology healthcare provider has to create an access to the system and uploading his/her electronic signature. Once the study PI needs to submit a new study, he/she will choose the study team member from a drop list, filling all the elements, uploading all study submission package, getting the approval from the oncology chairman, and then finally sending to the Research Committee/Institutional Review Board through the system.

Trial master file (TMF)

P: Regardless of the study type, the CRU team must keep all original essential study documents in secure cabinet in the unit, each study file consists of 3-4 binders along with patient case report form and shadow file, so approximately we have to save a place for 5-7 files for each study. Furthermore, we have to store the study related files for 10 years as per our institutional policy which gives us an extra burden in finding a huge secure archiving place.[4]

E: A simple electronic system was created to save and organize all study related essential/ source documents in hospital server. We categorize each study binder as per GCP requirements, provide an access to each study team member for their own studies only which allows an access to any study documents anytime anywhere without the help of CRU personal.

A backup paper master file is still available upon request.

Case report form (CRF)

P: A paper CRF was the most convenient way to collect the study data for whole study team member, as they can take such piece of document and collect the research data in a timely manner at any place. Moreover, it gives an easy access during any audit, initial/ date the changes, signing study data queries, and do quality check for database entry. The CRU team has to store the study CRF binder and shadow file for each study enrolled patient with all original signed copies of source documents.

E: An electronic CRF is used for most of our research projects either sponsored or investigator initiated one. A training session once the study is initiated conducted to the CRC, data entry and quality checkers.[5,6]

Consent process documentation

P: The consent form process for any new enrolled patient has to be documented in the patient's medical record, the study clinical research coordinator (CRC) needs to follow closely with study PI/sub investigator about the correct entry for all required elements needed as per GCP/ study protocol for each eligible patient, this process is subjected to human error and inappropriate utility of CRC time.

E: A research consent form documentation template created and uploaded in the electronic health record (EHR), so once the patient enrolled in the trial, the PI/sub investigator will open this form and check all related steps has to be discussed through the process and enter limited information related to the study number, consent date, consent version and signature date then will be saved automatically in patient's EHR.

Flag patients on clinical trial

P: Once a patient signs an approved informed consent, we make a copy to the patient and another to save it in the paper medical record. As per our policy, flagging the patient's record must be done immediately after enrollment. For that, we used a customized study label to flag the paper patient medical record from outside which reflect their participation in a clinical trial for study time duration period. We faced a challenge when a new paper medical record volume is added, we have to make a new label for the current volume used, plus moving the signed copy consent to the current one.

E: Once the study is approved by the IRB, we uploaded the study related information (study PI, title, study approved number and contact information) in the EHR. After that, when the patient enrolled, the study CRC will flag the patient in the specific trial by using easy drop menu list which will be saved until the patient withdraw or complete his/her study participation.

Reporting serious adverse event (SAE)

P: We used a paper SAE form which consists of around 3-7 pages per event, after that sending it to IRB using official memorandum. This process was challenging in order to follow the reporting within 24 hours as per GCP.

E: A hospital software was created to submit any SAE events to IRB using a standard template for all studies, which assure proper reporting and completion.

Correspondence between all parties

P: The official hospital memorandum template was used to communicate about all study related activities throughout the study period. After that, we have to file and organize each memorandum in its correspondence study TMF. Tracking each memorandum from writing to archiving phase needs extra management and follow up from all parties.

E: The hospital introduced an electronic memorandum system for any communication, this step helps us tremendously to send, track, save and flag any memorandum sent in a secure way.

Health record

P: From research perspective, the study PI/sub investigator has to document all patient's data in the paper medical record, then the study CRC has to check the completion entry in the source documents before transcribing it into the case report form (CRF) which includes the PI/ Sub-investigator documentation, medication order, laboratory/ radiology results, investigator pharmacist order, admission note and other data required per the study protocol.

Furthermore, the process of ordering and viewing the study patient medical record from medical record department, is a time and efforts consuming as we have to submit the request two days in advance. This long process happens every time we need the medical record for any reason such as internal audit, sponsor monitoring or inspection visit.

E: When our hospital starts using EHR, we customized the system to help in improving our research related procedures such as creating specific templates for study medication entry, enrollment and study visits documentation. This practice affects our research management through improving the research documentation process for our staff and decrease the volume of missing information.[7]

Department policy and procedure (DPP)

P: The access to our paper DPP was limited to CRU personnel and per request from any study team member interested in enriching their knowledge about CRU roles and function.

E: All CRU related DPPs, workflow, templates, study log forms are available at our departmental website (intranet) which increases the number of researcher's awareness of CRU structure, functions and encourages them for more participation in all study types.

Table 1: Comparison between the challenges and advantages per each element.

Elements	Challenges	Advantages
Study submission	-Lack of electronic system skills in most of PI/sub investigators, which requires a series of training sessions in each step and maintain a scheduled hands on training for any current/new staff.(8)	-Easy submission process with tracking feature that keeps the PI updated on all Research Committee/Institutional Review Board quires and process.
Trial master file	-Maintain confidential research data, a specific user ID and password has to be created and updated for each new study PI/sub investigators to access any research electronic system.	-Secure storage of all source documents. -Availability of any study related documents to all authorized study team member at any location of hospital.(9) - Saving staff time
Case report form	- Complexity of some sponsored e-CRF which required a couple of training sessions from study CRA. - Maintain a scheduled backup system for the research database.	-Effective management of any data entry/ data queries -Cost reduction, storage saving from paper CRF use.
Consent process documentation	- Continuous management/internal audit is necessary to ensure accuracy to an acceptable degree.	- Maintain high quality and effective consent process documentation.
Flag patient in clinical trial	- Update the approved studies list in the EHR in timely manner.	-Improve research patient safety and multidisciplinary care through proper flagging system.
Reporting serious adverse event	- Training in reporting SAE software.	-Improve timely SAE reporting process within 24 hours.
Correspondence between all parties	- High administration and supervision skills to maintain accurate and complete file.	- Proper tracking, storage and filling system of study correspondence.
Health record	- Frequent follow up and internal audit is required to check on the EHR completion of all source documents.	- Increase the efficiency and quality of CRU personnel team work. -Quality improvement of study Monitor/Auditor time during their visits. - Easy research data access.
Departmental policy and procedure (DPP)	-Continuous supervision in maintaining the updated version.	-Easy access to CRU related activities, standards and training sessions.

Up to the authors best knowledge, this is the first paper describing the detailed paperless CRU transition, its relevant that many hospitals/ institutions are in a transient phase between traditional paper-based use and electronic healthcare information systems, so there are many opportunities for expanding our paperless CRU model to another clinical trial unit in areas other than oncology and in other hospitals utilizing their available resources and implementing our practice to serve all health care providers interested in improving the clinical research management process.

Technology will continue to change the research practice in different dimensions, so the CRU team must keep their knowledge up to date about any new advancement in the field and think proactively about how to utilize it for the interest of research outcome without jeopardizing the research quality or breaching the ethical and the scientific standards.

REFERENCES

1. Menachemi N, Collum TH. Benefits and drawbacks of electronic health record systems. Risk Management and Healthcare Policy. 2011;4:47-55.
2. Levy R, Pantanowitz L, Cloutier D, Provencher J, McGirr J, Stebbins J, et al. Development of electronic medical record charting for hospital-based transfusion and apheresis medicine services: Early adoption perspectives. J Pathol Informatics. 2010;1:8.
3. Divate U, Das S, Bhosale N, Divate P. Best practices sharing: Setting up a professional clinical research unit in India. Perspectives in Clin Res. 2014;5(1):37-40.
4. Gupta SK. Paperless clinical trials: Myth or reality? Indian Journal of Pharmacology. 2015;47(4):349-53.
5. Sulaiman S, Alias RA, editors. Information Ethics in Malaysia Paperless Hospital." Proceedings of the Postgraduate Annual Research Seminar; 2006.
6. Missinou MA, Olola CH, Issifou S, Matsiegui PB, Adegnika AA, Borrmann S, et al. Short report: Piloting paperless data entry for clinical research in Africa. Am J Trop Med Hyg. 2005;72(3):301-3.
7. Hippisley-Cox J, Pringle M, Cater R, Wynn A, Hammersley V, Coupland C, et al. The electronic patient record in primary care--regression or progression? A cross sectional study. BMJ (Clinical research ed). 2003;326(7404):1439-43.
8. Krish T, Simon dL, Nikki S. Paperless practices: a report from a research network. Informatics in Primary Care. 2002;10:89–94.
9. Afrin LB, Kuppuswamy V, Slater B, Stuart RK. Electronic clinical trial protocol distribution via the World-Wide Web: a prototype for reducing costs and errors, improving accrual, and saving trees. J Am Med Info Assoc. JAMIA. 1997;4(1):25-35.