Solution when Global Pandemic resurrects paper-based PROs creating collection headaches for Data Managers

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ABSTRACT

Unforeseen COVID-19, country wide lockdowns and site closures impacted data collection processes, shifting eCOA data collection to paper assessments. This paper explores the challenges of processing urgent paper assessments, estimated at 6 months to complete. Using dynamic worksheets, integrated with each study's SQL database, allowed accurate and efficient data entry. eCOA systems employ parent/child relationship database models, allowing dynamic question entry in logical order. The solution mirrored this approach for paper, maintaining data integrity and providing a logical/simple tool for Data Management. Dropdown selection boxes dynamically updated on selected choices, permitting only the correct options. Translations were implemented, applying the applicable language to reduce inaccuracies. Current processes leveraged existing verification step prior to committing, creating staging tables which were validated by another individual for accuracy. Resulting in large volumes of paper assessments being processed in a fraction of the time and cost.

INTRODUCTION

Electronic Clinical Outcomes Assessments (eCOA) is the fastest growing technology in the eClinical space. It allows subject and site data to be captured in real time, accurately and with languages included in the protocol. In the rare event of device failure, a workaround is necessary to ensure data is still collected. These backup solutions may require capturing data on paper and manually entering into the system. This process requires more effort, is time consuming and can also increase the risk to data integrity.

With the unexpected arrival of COVID-19, the requirement for paper assessments suddenly increased. Global lockdowns resulted in sites closing and subject visits being cancelled. To ensure continuity of data collection, subjects either completed paper assessments at home or provided responses to sites via telephone interviews, which sites, in turn, transcribed onto paper..

Paper assessments were no longer the backup solution – they were the primary solution. As such, using the existing, inefficient process of entering paper data into the eCOA database,was not a viable option. An alternative approach was needed, one that was scalable, could support several languages, whilst maintaining high data integrity. The process of submitting the assessments also needed to be simple and easy, ensuring any additional burden on the site staff was kept to a minimum.

This paper looks at both the overall process and technical solutions implemented to allow a large volume of critical paper assessments to be entered.

KEY REQUIREMENTS

When devising a solution, several key requirements needed to be considered from both a site/sponsor perspective, as well as from a data entry viewpoint.

Site/Sponsor requirements

Minimize burden to site staff

One of the many benefits of utilizing eCOA in clinical trials is that the devices do all the hard work. The site staff review the questionnaires with the subjects and provide guidance on how to use the tools, but the data is captured and synced automatically to the system with minimal effort from the site staff. When capturing the data on paper, it was important that the data submission process was kept simple and easy, avoiding too much additional work on the site staff.

Maintain high data integrity
When capturing data electronically, it is captured in real time, stored securely on the device and uploaded to the central server during a manual or automatic sync process. When captured on paper, the data is not automatically uploaded, but manually entered. This manual interaction can increase the risk of error, therefore, the solution needed to use automation, where possible, and implement a verification step to ensure accurate data entry.

No change in how data is stored or transferred
Although the process for capturing and entering the data is different, how the data is stored once in the system and then transferred to external systems should remain the same. The sponsor should not 'see' any difference in the overall process.

Data available quickly
As data cannot be entered in real time, it is important to ensure that, once submitted, the data is entered quickly to avoid any issues with subject eligibility, randomization, or delays to subject visits. The solution needed to consider how paper assessments can be entered quickly to avoid downstream issues.
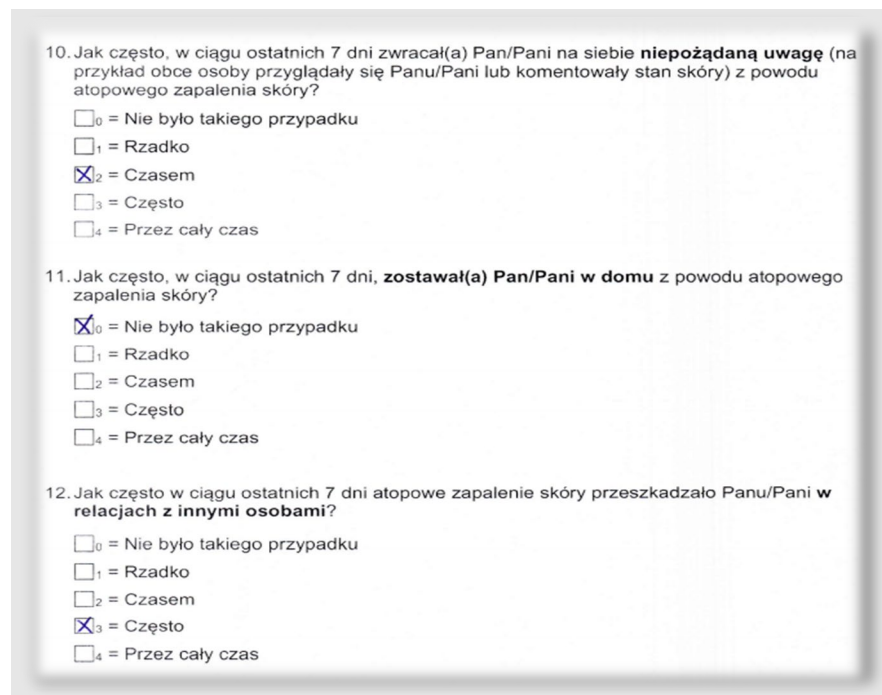
Data Entry Requirements

Scalable across multiple studies and PROs
With a high volume of paper assessments expected across several studies, all utilizing different PROs, the solution needed to be scalable to ensure efficient data entry. It should also be logical and simple to use.

Eliminate language barriers
With COVID-19 being a global pandemic and countries worldwide being impacted, it was essential that subjects and sites could still complete the paper assessments in the subject'snative language. The solution needed to consider how English-speaking Data Managers would be able to read and transcribe those answers accurately.

Figure 1 An example Non-English Assessment

Cost effective
With all new solutions, cost is a factor that needed to be considered. The solution needed to leverage existing resources and tools, where possible, to keep cost to a minimum.

THE SOLUTION

To minimize the burden on the site, paper eCOA screen reports, which mimicked the electronic devices, were provided. These were available in the subject's native language so questions could be understood, and answers could be documented quickly and accurately.

The existing Data Correction process was used for the submission of the assessments, again keeping the approach consistent and minimizing any inconvenience to the site.

The solution used native connectors between SQL and dynamic worksheets, allowing live data to be pulled down and used. Like other clinical data systems, eCOA systems often utilize a relationship database model to drive data relationships. This parent/child relationship is driven by Protocol > Questionnaire > Question > Choices and is maintained in a RTSM SQL database. To maintain data integrity, and to provide a logical means for the Data Managers to process the paper assessments, the solution utilizes the data relationships to ask questions to our Data Management team, in logical order.
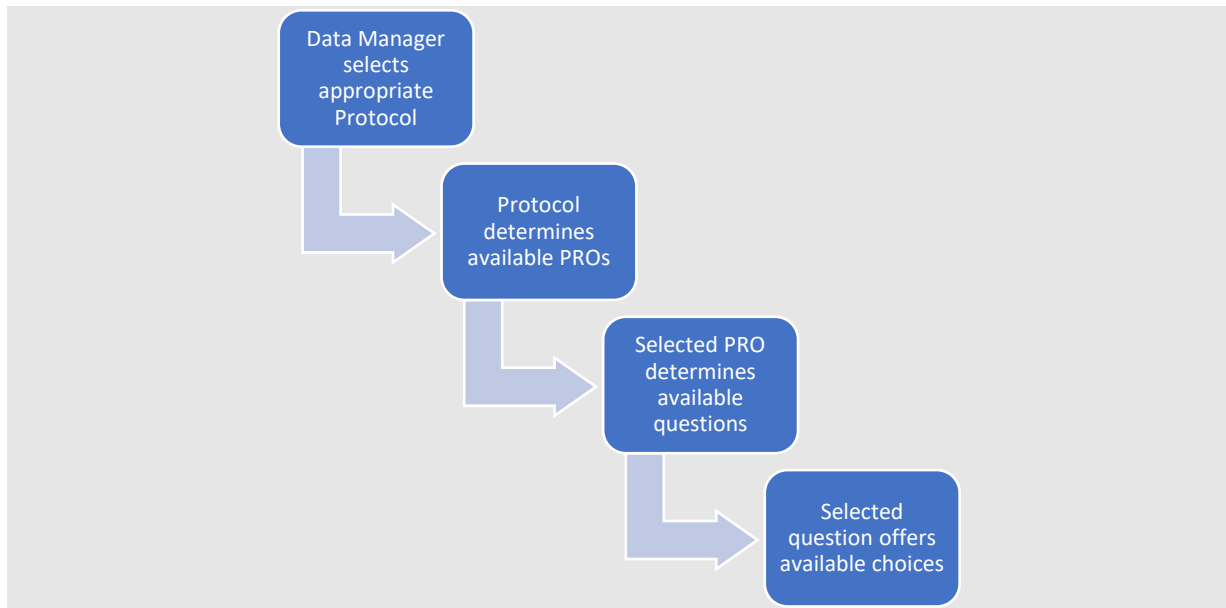
Figure 2 Data entry process flow

This approach, while very simple, allows the data manager to have clear and distinct choices without viewing or seeing data that is unrelated to the paper questionnaire.

Answer data is not usually stored in free text, meaning choice responses are saved in the database as an ID value. When processing paper questionnaires, it is critical that data can be entered using human readable prompts. Manually mapping IDs to choices would be highly inefficient and vastly heighten the risk of error to the process. To mitigate this risk, the solution provides an automatic mapping of human readable choices to ID, so that as data is captured, the relationship between the human readable text and system IDs is maintained.

Step 1	Database Name		QuestionnaireType	Clinician			
Step 2	Questionnaire Name	Investigator-rated Facial Wrinkle Scale Answer Sheet Frown Lines | Facial_Wrinkle_Scale_with_photonumeric_guide_(FWS)_Site | 1	QuestionnaireID	E06FE47D-126F-E811-80E3-000D3A1029A9			
Step 3	Subject Number		PatientID				
Step 4	Visit (Keep Empty for HH Questionnaires)	Day 1 Followup (Day 14)	Projected Date	2020-02-13 00:00:00.0000000 +03:00			
Step 5	Enter Visit Date (Date Only and empty for HH questionnaires)	11-Feb-2020					
Step 6	Enter Diary Start (Date and Time)	11-Feb-2020 00:00	Dup Questionnaire Data Entry	No			
Step 7	Enter Diary End (Date and Time)	11-Feb-2020 00:00	Complete?	Yes			
Step 8	Enter Zendesk Ticket (Number Only)		Data Entry Override?				
Step 9	Select Culture Name (Optional)						

Question #	Question Text	Question Choice	Free Text Entry	Question Input Type	Question Required?	Question Min
Question 1	1. Glabellar Lines (at rest)	0 = None | 0		RadioButton	Y	
Question 2	2. Glabellar Lines (at maximum frown)	0 = None | 0		RadioButton	Y	

Figure 3 Example completed worksheet

Another key requirement was allowing subjects to complete native language assessments, however, this posed a unique challenge as the Data Managers were English speaking. To reduce the risks, the solution allows for the question and answer text to appear in both English and the patient specific language. This allows the Data Manager to quickly identify the desired response even for symbol-based languages.

The industry's expectation is that any manual data entry be double-entered or verified, prior to being committed to the dataset. It is never appropriate to write data directly to the database without this verification being completed. As a response, a custom macro was created which loops through the selections and pushes the data back into SQL. This is stored in a Staging Table.

	InsertID	VisitDate	QuestionnaireID	QuestionID	ChoiceID	
1	21217254-2a54-4595-b858-f8eb5cd0e093	2020-10-05	D039027D-7DB4-E911-A820-000D3A17CD76	5923CB6D-7FB4-E911-A820-000D3A17CD76	C7BC1E95-7FB4-E911-A820-000D3A17CD76	2
2	21217254-2a54-4595-b858-f8eb5cd0e093	2020-10-05	D039027D-7DB4-E911-A820-000D3A17CD76	71ED6E66-80B4-E911-A820-000D3A17CD76	47AB3CBD-80B4-E911-A820-000D3A17CD76	
3	21217254-2a54-4595-b858-f8eb5cd0e093	2020-10-05	D039027D-7DB4-E911-A820-000D3A17CD76	8884532B-81B4-E911-A820-000D3A17CD76	40B25C59-81B4-E911-A820-000D3A17CD76	
4	21217254-2a54-4595-b858-f8eb5cd0e093	2020-10-05	D039027D-7DB4-E911-A820-000D3A17CD76	DC2D9B18-82B4-E911-A820-000D3A17CD76		2
5	ab11344a-6d01-49e8-8c5c-9b04843e354c	2020-10-05	2B0622FE-56B4-E911-A820-000D3A17CD76	170558B1-5EB4-E911-A820-000D3A17CD76	E29A0DBA-5EB4-E911-A820-000D3A17CD76	a
6	ab11344a-6d01-49e8-8c5c-9b04843e354c	2020-10-05	2B0622FE-56B4-E911-A820-000D3A17CD76	24A568F6-5EB4-E911-A820-000D3A17CD76	8FBAC1FF-5EB4-E911-A820-000D3A17CD76	a
7	ab11344a-6d01-49e8-8c5c-9b04843e354c	2020-10-05	2B0622FE-56B4-E911-A820-000D3A17CD76	97B11784-5FB4-E911-A820-000D3A17CD76	514F298D-5FB4-E911-A820-000D3A17CD76	a
8	ab11344a-6d01-49e8-8c5c-9b04843e354c	2020-10-05	2B0622FE-56B4-E911-A820-000D3A17CD76	3267D4C3-5FB4-E911-A820-000D3A17CD76	AC8F5BCB-5FB4-E911-A820-000D3A17CD76	a
9	ab11344a-6d01-49e8-8c5c-9b04843e354c	2020-10-05	2B0622FE-56B4-E911-A820-000D3A17CD76	C506CA2B-60B4-E911-A820-000D3A17CD76	E32AA732-60B4-E911-A820-000D3A17CD76	a
10	ab11344a-6d01-49e8-8c5c-9b04843e354c	2020-10-05	2B0622FE-56B4-E911-A820-000D3A17CD76	F39D508C-60B4-E911-A820-000D3A17CD76	0D038994-60B4-E911-A820-000D3A17CD76	a
11	ab11344a-6d01-49e8-8c5c-9b04843e354c	2020-10-05	2B0622FE-56B4-E911-A820-000D3A17CD76	4F1134E2-60B4-E911-A820-000D3A17CD76	A8A3D2E9-60B4-E911-A820-000D3A17CD76	a
12	ab11344a-6d01-49e8-8c5c-9b04843e354c	2020-10-05	2B0622FE-56B4-E911-A820-000D3A17CD76	7829D02E-62B4-E911-A820-000D3A17CD76	5575E737-62B4-E911-A820-000D3A17CD76	a
13	ab11344a-6d01-49e8-8c5c-9b04843e354c	2020-10-05	2B0622FE-56B4-E911-A820-000D3A17CD76	F44D058A-65B4-E911-A820-000D3A17CD76	85FAA19A-65B4-E911-A820-000D3A17CD76	a

Figure 4 Example Staging table

Linking this to a verification worksheet allows error checks and manual verification to be performed on the data, prior to it being committed to the database. Verification can also happen in both English and the native language, allowing the verifier to see the data side by side with the paper questionnaire with native language text.

		Investigator-rated Facial Wrinkle Scale Answer Sheet Frown Lines | Facial_Wrinkle_Scale_with_photonumeric_guide_(FWS)_Site		6a9ac260-24bf-43d9-819f-1c0d4ba87dda
Step 1	Select Zendesk Ticket to Review		InsertID	
Step 2	Enter Email Address To Sent Script (Optional)		Approved/Rejected By	
Step 3	Select Culture (if not English)	en-US		
Step 4	Include English with other Culture?			

Row Number	Data Point	Value
1	InsertID	6a9ac260-24bf-43d9-819f-1c0d4ba87dda
2	DBName	
3	PatientNumber	
4	VisitID	5
5	VisitName	Day 1 Followup (Day 14)
6	VisitStatusAfterScriptRun	Complete
7	VisitDate	2020-02-11 00:00:00.0000000 +03:00
8	DiaryStart	2020-02-11 00:00:00.0000000 +03:00
9	DiaryEnd	2020-02-11 00:00:00.0000000 +03:00
10	ZenDeskTicket#	
11	UserWhoInserted	
12	QuestionnaireName	Investigator-rated Facial Wrinkle Scale Answer Sheet Frown Lines | Facial_Wrinkle_Scale_with_photonumeric_guide_(FWS)_Site | 1
13	1. Glabellar Lines (at rest)	0 = None | 0
14	2. Glabellar Lines (at maximum frown)	0 = None | 0

Figure 5 Example validation worksheet

CONCLUSION

Thinking back to the key requirements, the solution met both the needs of the Sponsor/Site and the Data Managers.

Due to the simple collection and submission process, the burden on the sites/subjects was kept to a minimum. The validation process ensured that the data integrity was maintained and the process for storing and transferring the data was unaltered. As the solution was logical and used worksheets, data could be entered quickly, resulting in a time saving improvement of 120% compared to the previous paper back up solution. It could also be used by multiple Data Managers, allowing data entry 24/7.

The implementation of dynamic mapping from study specific SQL databases ensured the solution was scalable across multiple studies and PROs. The option to change the question and answer text to the required language, for both data entry and verification, eliminated any translation concerns and improved overall data integrity. Building the tool in house, using existing tools and resources, kept the solution effective.

CONTACT INFORMATION

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