Flexible Approaches to ePROM Data Collection in Clinical Trials: Concerns of Instrument Developers and Copyright Holders

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Content

Introduction

Most electronic patient-reported outcome measures (ePROMS) require licensing and approval for electronic implementation prior to use in research settings. Instrument developers can assign the licensing responsibility and approval for the electronic implementation to a third-party organization or require both themselves and copyright holders to provide approval. While the benefits of electronic data collection in clinical trials (CTs) are well-documented[3-12], instrument developers/copyright holders remain vigilant around the implementation of their measure(s) to ensure their measurement properties and scientific integrity are maintained.

When ePROMs are used to support endpoints in CTs, regulatory bodies may request evidence demonstrating comparability to paper formats[13], adding cost and time to the trial start-up. Several ISPOR task force reports have addressed the need for comparability testing between different modes of data collection; the most recent recommends that qualitative and/or quantitative comparability testing is not necessary when ePROM design best practices have been followed and there is sufficient evidence in the literature to support the comparability of the

response scale types being migrated[14-16]. This demonstrates the progress the scientific community has made in increasing the evidence base for paper-to-electronic migrations and removing inefficiencies in the process[13].

There is also an increasing impetus to add remote capabilities to trials to allow better accessibility for under-represented populations in trial samples and reduce burden. While remote data capture in CTs is not a new concept and certain patient-reported outcome measures (PROMs) have routinely been collected outside of the clinic, wider adoption was spurred on by the COVID-19 pandemic. This presented a unique use case for requiring flexibility and adapting current trial designs to continue clinical research during the pandemic.

Nevertheless, barriers to efficient ePROM implementation still exist. CT sponsors and eCOA[1] providers have identified that instrument developers'/copyright holders' electronic implementation requirements, license requirements when using electronic modes, screenshot review, and on-device testing continue to present key challenges during CT start-up. Often instrument developers/copyright holders are not experts in ePROM implementation or aware of the ever-evolving best practices, leading them to make outdated recommendations for their instruments.

This study aimed to identify instrument developers'/copyright holders' concerns surrounding electronic implementations, describe the flexible approaches they permitted during the pandemic, and understand their willingness to allow similar approaches moving forward.

Summary of Results

The response rate was 32.3%, with 11 respondents completing the questionnaire items (Table 4). Table 5 shows that the majority (81%, n=9) of the participants worked for organizations that controlled the license for at least 4 instruments, including 45% (n=5) controlling more than 11 instruments. The time needed for licensing varied among respondents (from 0-1 week up to 13+ weeks), with most responses at 2-4 weeks (36%, n=4) (Table 5).

Each of the 17 listed concerns with electronic implementation was endorsed by at least 1 respondent. Respondents endorsed, on average, 6 concerns (see Table 1 for a breakdown of responses).

Of the 8 respondents who completed the section on flexible approaches allowed for during the pandemic, 50% (n=4) reported allowing multiple flexible approaches (see Table 2 for details on items endorsed; response options were not mutually exclusive). Finally, of the 10 respondents who completed the question on their willingness to allow flexible approaches in the future, 70% (n=7) reported they would.

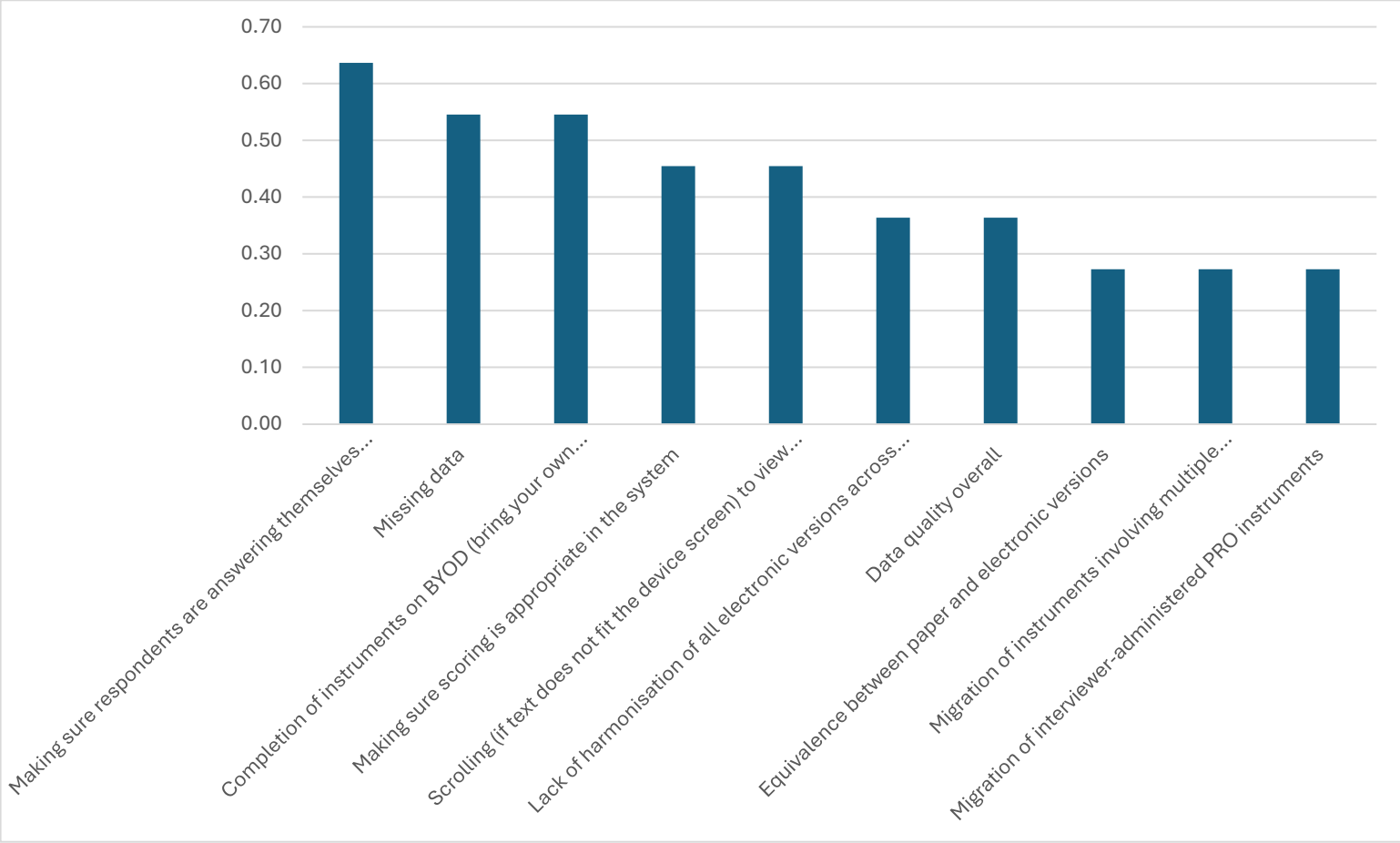
Table 4 - Type of respondents

		N	%
Category 1	Copyright holder/instrument developer/instrument licensor or distributor	9	82%
Category 2	Scientific expert involved in the process of migrating and translating standardized licensed instruments	2	18%

Respondent Concerns and Recommendations

In this section we provide recommendations for the most commonly reported concerns.

Do you have any of the following general concerns with the electronic implementation of your instrument(s)? (N=11) *Full table available here**



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Who Completed the ePROM?

Making sure respondents are answering themselves when at home

A key component of data integrity in line with the FDA ALCOA+ principles ("Attributable, Legible, Contemporaneously recorded, Original or a true copy, and Accurate")[18] is that data are attributable, i.e., traceable to the individual who reported them. In a remote setting, ensuring participants are responding for themselves was endorsed as a concern for 64% (n=7) of respondents, which may stem from a lack of understanding of security in eCOA system design.

Regulatory guidelines specify the requirement for access controls that ensure only authorized individuals use the electronic system[19]. Self-selected secure access codes (e.g., PINs) provide a robust solution ensuring the desired respondent is entering the data. Ensuring attributable data is more challenging for paper PROMs, specifically outside of the clinic environment, yet seemingly electronic approaches are held to a higher level of scrutiny, despite providing solutions to most data quality and integrity issues encountered with paper implementations.

Furthermore, site and participant training on the technology used to capture PROMs is a core part of trial start-up20 with many regulatory agencies highlighting the importance[21-28]. Training should emphasize that only the participants themselves should respond to PROMs and should provide information about the helpdesk and/or other support resources that are available.

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Why Didn't They Respond?

Missing Data

As PROMs are increasingly used to support primary and secondary endpoints in the evaluation of new medical products and in reimbursement decisions, data quality is critical. A long-held concern regarding PROMs is missing data[29], also called out in regulatory guidance[26]. This remained a key concern for respondents (55%, n=6), highlighting the importance of informing and educating relevant stakeholders about the features of eCOA systems to actively mitigate missing data.

A key benefit of ePROM data collection, as compared to paper, is the ability to reduce missing data. On paper, a respondent may not complete an item, either accidentally or intentionally, and it is often impossible to query missing data. Electronic implementations can require respondents to enter a response to an item before proceeding to the next item, providing a clear opportunity to mitigate concerns around missing item-level data[30]. Where respondents are not required to provide a response to an item, an edit check can be implemented requiring confirmation of their intention to skip the item, facilitating management of missing item-level data during statistical analysis.

Missing data at the whole-measure level is more difficult to mitigate. However, another key feature of electronic systems is the ability to program notifications when ePROMs are due to be completed (e.g., push notifications/short message service [SMS]) to increase compliance, as recommended by regulatory guidance[25]. Furthermore, sites can monitor real-time compliance, follow-up with participants, and re-iterate the importance of ePROM data collection. It is also important to provide information on available back-up options (e.g., web back-up) in the event of device/technology failure, which can impact missing data at the whole-measure level.

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Did the ePROM Display Correctly?

Completion of instruments using BYOD approaches

Traditionally, participants have been provisioned devices solely for ePROM-related trial activities. Recently, participants are being given the option to use their own device (smartphone, tablet, computer) to complete ePROMs, using either an app- or web-based approach–so-called BYOD, which can reduce participant burden by avoiding the need to manage multiple devices and improve ease of participation[31]. Participant familiarity with their own device creates the potential for increased participant engagement and compliance with data collection requirements, reducing missing data[32]. The main concern with BYOD endorsed by respondents was accessing the measure using web browsers that are not optimized for display on mobile devices (55%, n=6). With BYOD, participants can use multiple device types and models; respondents may be concerned about consistent display of their measures when BYOD approaches are used, because it is not feasible to review the implementation on all possible device types. Interestingly, there was less concern around app-based BYOD approaches (18%, n=2), which are designed to scale to screen size and for the smaller screen of smartphone-type devices. The web-based approach is likely more of a concern for respondents as there is less control over the display properties when rendered though a browser compared to an app. Regarding the reliability and validity of remote ePROM data collection using BYOD, there is an expanding body of evidence demonstrating that for common response scale types, respondents answer consistently across modes of data collection, including BYOD formats[32-34]. eCOA providers should have processes in place to ensure consistency of the ePROM presentation across different operating systems (e.g., Android, iOS), browser types (e.g., Chrome, Edge, Firefox, Safari), screen sizes, and screen resolutions. These strategies should consider technology, hardware, and linguistic aspects. Many eCOA providers implement a check to detect the operating system version and browser type to prevent download/access if an inappropriate browser and/or OS version is used. In these instances, provisioned devices should be provided.

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Will the Data Add Up?

Making sure scoring is appropriate in the system

Most instrument developers have developed scoring guidelines, including the amount of item-level missing data allowed to still enable scoring. Five respondents (45%) reported concerns with appropriate scoring in the electronic system, highlighting the possibility that they are unclear about the process undertaken by eCOA providers to ensure this, or it may stem from complex scoring scenarios (e.g., reverse scoring, weighting).

When PROM scores are generated solely for statistical analysis of the endpoint, it is not necessary to conduct scoring in the eCOA provider's system. However, where the score is used to support a decision point in a trial (e.g., eligibility, stopping criteria), it is commonplace for the eCOA provider to implement this scoring within their system following the guidelines specified by the instrument developer and in consultation with the trial sponsor and their protocol. This should be tested as part of the provider's internal quality assurance and technical validation process, and the sponsor's user acceptance testing (UAT) process. Compared to scoring conducted manually by the site on paper, scoring implemented in electronic systems drastically reduces the risk of miscalculation.

It is beneficial for instrument developers to provide complete guidelines in scoring manuals, e.g., specific algorithms that can be copy-pasted, to avoid transcription errors and reduce the risk of misinterpretation of scoring rules. Often, scoring instructions are detailed in the original validation manuscript, which can be challenging to obtain when not published as open access. Further research is needed to understand any other concerns related to ensuring appropriate scoring in the system to rectify any issues with the current process. Providing education to instrument developers/copyright holders around current practices related to scoring implementation will help mitigate such concerns.

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Will Scrolling or Zooming Impact Responses?

Scrolling in electronic implementations was endorsed as a concern by 45% (n=5) of respondents. As a greater focus starts to be placed on ensuring the accessibility of electronic systems (as highlighted by the recent FDA PFDD Guidance)[27,28], the use of scrolling has increased, where users are required to scroll down to view all item information before they can provide a response and proceed to the next item.

Implementing a single item per screen is the current industry standard[15,35] but it is important to consider that, in the absence of scrolling, on smaller screen sizes this practice may inhibit accessibility, for example, due to a small font size that limits readability. To address readability concerns, there could then be a need to split response options across two or more screens, increasing the risk of jeopardizing the measurement properties. None of the above are desirable solutions, therefore, using scrolling can address those concerns. With BYOD approaches, scrolling is likely to become more commonplace because of the wide range of screen sizes and resolutions utilized in participants' devices. Many instrument developers do not permit scrolling due to concerns around measurement comparability when not all response options are viewed at once. However, a recent article from the eCOA Consortium updating ePROM migration best practices[35] recommends "enabling scrolling rather than ... reducing the font size to avoid causing reading difficulties." The article provides options for implementing scrolling functionality with the relevant safeguards, based on recent evidence that vertical scrolling is unlikely to have a negative impact on PROM measurement properties[36]. In instances when disabling scrolling would limit readability, we encourage further conversations with instrument developers/copyright holders to determine the appropriate implementation that will reduce any negative impact on usability or comparability.

Interestingly, allowing participants to zoom, which may also lead to the full item not being viewed all at once, was less of a concern (27%, n=3), while having a minimum device size and resolution specified was only

endorsed by 18% (n=2). The impact of zooming on measurement properties has not been investigated to our knowledge. Further research is required to inform the best strategy and develop best practice recommendations to implement relevant safeguards for zooming[35].

There is still some work needed to communicate the latest evidence on optimal electronic implementation to reassure CT stakeholders that relevant safeguards are implemented to ensure that the entire item information is viewed before the participant can progress to the next item. It is important to highlight that the primary reason for scrolling and zooming is to improve user accessibility. These accommodations can be provided in a way that ensures the validity and integrity of the measure.

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Will these Changes Impact the Data?

Data Quality

Concerns around data quality were endorsed by 36% (n=4) of respondents. The quality of PROM data is critical and integral to the success of a CT and ensuring data quality will always remain a guiding principle for eCOA providers and sponsors. The following free text comments: "*the quality of the data is related to the quality of the implementation*" and "*the necessary time must be given to properly implement and test an application*" suggest that if user acceptance testing (UAT) is conducted[37], that ePROM implementation best practice recommendations[35] and specific guidelines from instrument developers are followed, and that proper quality checks and review time are allocated, then concerns around data quality may be mitigated. Electronic data collection also reduces the risk of participants completing multiple days of reporting all at once (the so-called "parking lot effect") resulting in more accurate, higher quality data[8,38].

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Were Changes to the ePROMs Consistent?

Lack of Harmonization

Lack of harmonization can refer to the lack of consistency in the electronic migration across eCOA providers, including changes to instructional text (e.g., “select” vs. “circle”), and was endorsed as a concern by 36% (n=4) of respondents.

As detailed earlier, the evidence base shows ePROM measurement properties are maintained when best practices for migration are followed[15,32,37,39], including minor changes to wording to align with the new mode of data collection. Effective communication and assurance that eCOA providers follow best practices would likely address this concern[16]. However, it is recognized that different providers may implement slightly differently alternatives (e.g., “select” or “choose”). To mitigate this inconsistency, instrument developers/copyright holders may consider developing their own source e-format for implementation, including translations, which one respondent reported having. Version control would then remain with instrument developers/copyright holders. Standards should be based on ePROM best practices to encourage harmonization across providers.

Four additional *Respondent Concerns and Recommendations* categories received fewer than four responses. Please find those details in the Appendix.

Accepted Flexible Approaches

Half (n=4) of the respondents to Section 2 reported allowing the following: interview administration of their measure without requiring a comparability study, web-based implementation of a measure in a trial as an alternative to a provisioned tablet used for data capture at a site visit, changes to licensing to allow for multiple modes of data collection and methods of administration, and conducting linguistic validation cognitive interviews remotely as opposed to physically face-to-face. Three (38%) respondents reported approving the use of their measures via BYOD, 1 (13%) allowed sponsors to skip usability testing, and 1 (13%) allowed usability testing to be conducted using a web-based emulation of the software screens, and where it was not possible to carry this out with participants, eCOA experts could perform it. One (13%) respondent also reported allowing sites to send cards containing response options to participants at home to facilitate the interviewer administration of their measure. . Finally, 1 (13%) respondent reported streamlining the licensing process as a flexible approach during COVID-19, and

another (13%) commented on having already streamlined the licensing process. . The license is usually specific to the mode used in the study (e.g., paper, app, web, tablet, BYOD), with the use of multiple modes often requiring separate licenses, yet during the pandemic, many copyright holders allowed “emergency” use of another mode prior to full licensing execution to prevent data collection disruption. Seeing the move towards more data collection flexibility and optionality in CTs, it may be beneficial for copyright holders to follow this approach, combining licensing agreements to one license per PROM.

During the pandemic, some copyright holders also performed certain activities associated with the licensing process in parallel with or after executing the license, such as screenshot review. It is unknown if this flexible approach will remain acceptable to copyright holders, though recent changes in the licensing process for the EuroQoL’s EQ-5D - disconnecting quality control processes and responsibilities from the license - might be a model other measure owners adopt.

The free text (“Other”) response revealed that 1 respondent had developed a Frequently Asked Questions (FAQ) document to advise users who needed to switch modes of data collection or methods of administration during COVID-19. Two respondents (25%) reported already allowing interviewer administration of their measures prior to the pandemic.

The third section of the questionnaire found that 70% (n=7) of respondents planned to allow flexible approaches to PROM data capture beyond the pandemic, while 30% (n=3) would not, of whom 1 (10%) reported they would consider it on a case-by-case basis. Of those not willing to approve flexible solutions going forward, one

inflexible pharma deadlines which are pushed down to vendors. eCOA vendors have not followed our recommendations on so many occasions that we updated our approach to ensure that we are not the risk bearers when things go wrong." Given flexibility is a spectrum, it is unclear what aspects of flexibility are believed by respondents to result in inaccurate data or increased risk. This warrants further exploration.

One limitation is the small sample size (n=11) due to the limited pool of participants with the expertise to participate in this study, as instrument developers/copyright holders are not a large population sample. Another study design, such as a Delphi panel, may have been a more appropriate approach to gather insight from a small group of experts. This limitation is mitigated by the fact that the sample represents one-third of those invited to participate, which is close to the range of response rates (34 to 44%) for an online survey study design reported in a meta-analysis published by Wu and colleagues[41].

Conclusion

Technology used to support clinical research has progressed significantly over the past decade, providing the ability to capture data both at traditional site visits and remotely. It is positive to see the willingness of instrument developers/copyright holders to embrace flexible data collection approaches for their measures, especially at a point where it was vital to the maintenance of ongoing trials providing much needed treatments to individuals. Nevertheless, electronic systems are still being held to a higher level of scrutiny compared to paper, despite providing solutions to most data quality and integrity issues encountered with paper implementations. Ensuring data quality is the heart of eCOA; most technologies developed in commercial clinical research offer robust safeguards and testing processes that address most of the concerns expressed. High quality and security in technology are also prerequisites for industry stakeholders[18,19,21-28]. Sharing information with and educating instrument developers/copyright holders about how eCOA systems function could alleviate most concerns.

We recognize that sponsors, eCOA providers, and instrument developers/copyright holders generally work in silos, leading to friction around implementations and approvals. Collaboration is key to translate the latest evidence into practice and communicate important research findings to all relevant stakeholders. Despite the flexibility reported during the pandemic and willingness to have continued flexibility, some instrument developers/copyright holders still require assurance that their concerns are addressed. It is important to recognize that flexibility has a different meaning across individuals and does not mean that anything and everything is permitted; rather, flexibility is about facilitating alternative evidence-based ways to provide optionality and remove potential barriers to CT participation, without affecting the integrity of PROMs or the resultant data. The barriers and concerns identified in

this paper continue and persist, however they can be addressed with acceptable solutions highlighted in industry good practices and available evidence. Again, education and collaboration between all stakeholders are key to managing this change. Further investigation may be needed to confirm the results post-pandemic and to examine through a larger sample size and qualitative interviews whether there had been any progress in the way instrument developers/copyright holders perceive electronic implementation of their instruments.

Appendix

RESPONDENT CONCERNS AND RECOMMENDATIONS *with fewer than four responses*

3/11

This concern was endorsed by only 27% (n=3) of respondents.

Will the eVersions Provide the Same Data?

Equivalence between paper and electronic versions

Although the term "equivalence" was used in the questionnaire completed by instrument developers/copyright holders, consensus in the field has moved to the term "comparability" as more accurate terminology. A great deal of evidence has been generated in the past 20 years demonstrating that paper and electronic modes of data collection generate comparable data. To ensure that comparability is maintained, a "faithful migration" from paper to electronic format should be conducted[15,16] following established best practice recommendations[35]. The recent publication of the updated ISPOR Task Force recommendations supporting comparability between modes of data collection provides further evidence to quell this concern[16].

RESPONDENT CONCERNS AND RECOMMENDATIONS *with fewer than three responses*

3/11

This concern was endorsed by only 27% (n=3) of respondents.

Will this Disrupt eCOAs for Multiple Respondents?

Migration of instruments involving multiple respondents

Measures comprised of reports from separate reporters (e.g., clinicians or caregivers in addition to patient) are rare but do exist (e.g., SCORAD [Scoring Atopic Dermatitis], C-ACT [Childhood Asthma Control Test]). For these types of measures, the specified order and timeframe to complete the respective sections must be considered (e.g., participant followed by clinician or in parallel), which is easier to manage and verify when implementing electronically.

Recommendations are to follow existing best practices for eCOA implementation, with additional consideration for facilitating multiple reporters' responding within the same timeframe in the order specified by the instrument developer's guidelines; remote data capture (e.g., completion during televisits) will require additional functionality. Ensuring attributability to each respondent is also important as previously detailed, and having unique access credentials for each respondent is already best practice.

3/11

This concern was endorsed by only 27% (n=3) of respondents.

Will this Disrupt ePROMs for Interviewers?

Migration of interviewer-administered PRO instruments

During the pandemic, administering PROMs to the participant via telephone interviews was used to collect data in instances where participants could no longer attend site visits in person. In some cases, site staff entered data participants reported directly into the ePRO device.

These concerns with this item may relate to the lack of clear processes describing how interviews are conducted in conjunction with electronic data collection. If not available from the instrument developers/copyright holders, the recommendation is to develop guidelines and interviewer scripts to ensure consistent administration across participants. Interviewers should be trained to minimize bias and enter exactly what the participant reported.

In instances where ePROMs are interviewer-administered for a select number of participants (i.e., due to inability to complete for themselves), flagging the data collection approach and ensuring appropriate credentials are entered during login is crucial to data authentication; the electronic implementation should include a defined interviewer login that is separate from the participant login. It is important to note, that such approaches are key to ensuring accessibility and that participants are not excluded from trials due to data collection methods.

2/11

This concern was endorsed by only 18% (n=2) of respondents.

Usability Testing (UT) for Specific Countries or Languages

UT examines whether participants from the target population can use the software and device appropriately. Historically, this has been conducted at the same time as migration and cognitive interviewing for comparability testing in the context of a specific measure. This process includes formal documentation of the ability to navigate through the measure, follow instructions, and respond to items in the electronic platform, ultimately ensuring completion as intended[14,40].

Literature and meta-analyses have demonstrated that most findings from UT will be eliminated when ePROM design best practices are applied and platform usability has been assessed in a range of patient populations that would be representative of individuals with varying differences in how they may experience the use of technology (e.g., age, dexterity ability, cognitive difficulties)[33]. Differing experience with technology use also extends to different countries and regions of the world, and so it is important that platform UT includes representation of this.

Table 1 – List of pre-identified general concerns with electronic implementation and responses (N=11)

Do you have any of the following general concerns with the electronic implementation of your instrument(s)? Choose all that apply	**N**	**%**
Making sure respondents are answering themselves (for BYOD/provisioned device at home)	7	64%
Missing data	6	55%
Completion of instruments on BYOD (bring your own device) using web browsers to access the instrument which are not optimized for display on mobile devices	6	55%
Making sure scoring is appropriate in the system	5	45%
Scrolling (if text does not fit the device screen) to view the full item stem and response options	5	45%
Lack of harmonisation of all electronic versions across modes	4	36%
Data quality overall	3 4*	27% 36%*
Equivalence between paper and electronic versions	3	27%
Migration of instruments involving multiple respondents (e.g., clinician and patient respond to separate sections of the same instrument)	3	27%
Migration of interviewer-administered PRO instruments	3	27%
Zooming (allowing respondents to magnify the font on the screen) causing item stem and response options to be not fully visible on the screen	3	27%
Usability testing for specific countries or languages	2	18%
Completion of instruments using web browser on laptop/computer devices	2	18%
Completion of instruments on BYOD (bring your own device) using a mobile app downloaded to the respondent's device	2	18%
Minimum device size and resolution	2	18%
Allowing interviewer administration of electronic PRO instruments for respondents who are not able to read and respond for themselves	1	9%
Completion of instruments on BYOD (bring your own device) using mobile web browsers optimized for display on mobile devices	1	9%
None of the above	0	0%

Other concerns (please explain in comments) (n=4/36%)

1. *"I have standardised all of these with a protocol for migration that all companies and organisation must follow before a license is granted."*

2. "*If completion is strictly electronic, then there may be a problem if a respondent has any questions about completion and there is no one there to help."*

3. "*Intellectual property. We would appreciate more consideration from the eCOA vendors of how these instruments were designed and that when the items or instructions are changed without due consideration of how they impact responses, then the instrument loses its ability to measure construct appropriately for patients and our clients."*

4. "*TIME! As with anything, it is critical to properly plan and allow for adequate time to implement and test an application properly. The quality of the data is directly related to the quality of the implementation."*

**Concern regarding data quality included in comments*

Table 2 - Flexible approaches allowed during COVID-19 pandemic and responses (N=8)

During the COVID-19 pandemic, did you allow any of the following to enable CTs to accommodate the necessary precautions? Choose all that apply	**N**	**%**
Interview administration of an electronic PRO instrument in a trial without requiring a prior equivalence study	4	50%
Web-based implementation of a PRO instrument in a trial as alternative to tablet at the site	4	50%
Changes to licensing to allow multiple modes under the same license	4	50%
Allowing linguistic validation cognitive interviews to be conducted remotely (via telephone or web-based platform) instead of in person	4	50%
BYOD (Bring your own device) implementation in a trial where respondents could use their own devices to complete the PRO instrument	3	38%
Streamlining of licensing process	1	13%
Skipping usability testing	1	13%

Other concerns (please explain in comments) (n=4/50%)

1. Already had interviewer versions before pandemic (n=2 /25%)
   - *"We already have interviewer versions".*
   - *"I already had validated paper interviewer-administered versions of my questionnaires."*

2. Sent response options to patients so clinic member could interview by phone (n=1 / 13%)
   - *"The seven-point response options were sent to patients so that a clinic member could do the interview by phone".*

3. Developed Frequently Asked Questions (FAQ) to advise users who were needing to switch modes due to COVID-19 (n=1 / 13%)
   - *"We came out with an FAQ for licensed users who were needing to switch modes mid-study due to COVID-19 to advise them, as we were getting a lot of questions."*

4. Already had streamlined process (n=1 / 13%)
   - *"We already have streamlined processes".*

5. Allowed specific processes:
   - "*Allowing checking of usability via emulator when not possible with devices; when usability testing with participants was not possible, conducted overall usability testing with eCOA experts (expert review). For BYOD, performed full screenshot review on first (smallest) device and checked overall usability of other device categories. Same for multiple device studies.*" (n=1 / 13%)
   - "*With exception of remote LV tasks, are flexible and allow these points to occur even outside of COVID.*" (n=1 / 13%)

Table 3 - Willingness to allow flexible approaches in the future (N=10)

Do you plan to allow flexible approaches to implementation (e.g., web-based, BYOD, or interviewer administration or mix of these) to support remote assessment of your instrument in future CTs?
Yes □ N=7 (70%) **No** □ N=3 (30%)
If No, please explain: 1. "*Will decide on a case-by-case basis".* 2. *"Flexibility breeds inaccurate data. All protocols for translation and migration must be followed exactly before a license is given."* 3. *"We have had to be flexible in the face of inflexible pharma deadlines which are pushed down to vendors. eCOA vendors have not followed our recommendations on so many occasions that we updated our approach to ensure that we are not the risk bearers when things go wrong."*

Table 4 - Type of respondents

		N	%
Category 1	Copyright holder/instrument developer/instrument licensor or distributor	9	82%
Category 2	Scientific expert involved in the process of migrating and translating standardized licensed instruments	2	18%

Table 5 - Number of instruments the respondents or their organization hold the license or copyright for, along with the average time (from start to finish) for the licensing process of one instrument within their organization

		N	%
Number of instrument licenses held	1-3	2	18%
	4-7	4	36%
	11+	5	45%
Average time for licensing of one instrument	0-1 week	2	18%
	1-2 weeks	2	18%
	2-4 weeks	4	36%
	13 weeks +	1	9%
	Not sure	2	18%

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List of Abbreviations

ALCOA+: Attributable, Legible, Contemporaneously recorded, Original or a true copy, and Accurate

BYOD: Bring your Own Device

C-ACT: Childhood Asthma Control Test

COA: Clinical Outcome Assessment

C-Path: Critical Path Institute

CT(s): Clinical trial(s)

eCOA: Electronic Clinical Outcome Assessment

ePROM(s): Electronic Patient-Reported Outcome Measure(s)

FAQ: Frequently Asked Questions

FDA: Food and Drug Administration

GBTI: Getting Better Together Initiative

GDPR: General Data Protection Regulation

ISOQOL: International Society for Quality-of-Life Research

ISPOR: The Professional Society for Health Economics and Outcomes Research

PRO: Patient-Reported Outcome

PROM(s): Patient-Reported Outcome Measure(s)

SCORAD: Scoring Atopic Dermatitis

TCA-SIG: Translation and Cultural Adaptation Special Interest Group

UAT: User Acceptance Testing

UT: Usability Testing

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