UKCRC Registered Clinical Trials Units

UKCRC Registered CTU Network – Report on the use of electronic safety reporting systems in clinical trials

UK Clinical Research Collaboration

igniting our potential

Report on the use of electronic safety reporting systems in clinical trials

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The aim of this work was to understand current practice and share findings with the wider UKCRC network. This Report has been written following a survey that was circulated to all UKCRC-registered CTUs and we are grateful for those that responded and shared their practice; allowing this piece of work to come together.

Contents

1. Abbreviations

AE – Adverse Event

CI – Chief Investigator

CRF – Case Report Form

CTU – Clinical Trials Unit

DMEC – Data Monitoring and Ethics Committee

DSUR – Development Safety Update Report

EDC – Electronic Data Capture

MHRA - Medicines and Healthcare products Regulatory Agency

NIHR - National Institute for Health and Care Research

PI – Principal Investigator

PV – Pharmacovigilance

REC – Research Ethics Committee

RSI – Reference Safety Information

SAE – Serious Adverse Event

IT – Information Technology

IS – Information Systems

2. Introduction

The “Smarter Ways of Working” Task and Finish Group was formed to address the need to develop and share best practice across the UKCRC network in relation to electronic serious adverse event (SAE) reporting systems. One of the key objectives of this group was to understand current practice and share these findings with the wider UKCRC community. A survey titled *‘Use of Online Safety Reporting Systems in Clinical Trials’* was conducted to fulfil this objective.

The survey was circulated to all UKCRC-registered CTUs in September 2022 and was formed of seven sections (Access, Managing Information, Notifications, Reporting Functionalities, System Specification, Availability & Usability and Development) which were designed to capture detailed information on the functionality of the systems used by each responding CTU.

Responses were received from 24 CTUs, of which 6 indicated that safety reporting at their unit remained fully paper based. This report summarises key findings from each of the sections to enable a comparison of different approaches, which will form the basis for future discussion on opportunities for development and collaborative work in this area.

2.1. Section 1 - Access

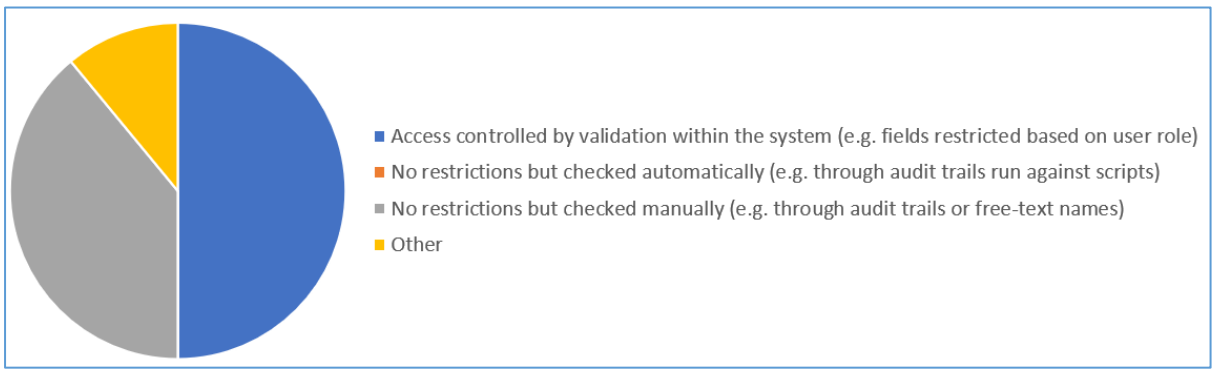
This section of the survey focussed on how access to the electronic reporting system was managed and how access could be restricted by user role and for blinded information. Of the 18 CTUs that reported use of some form of electronic safety reporting system, a slight majority of systems described were able to automate access confirmation.

User access to electronic systems was grouped as follows:

- Site team only: 1/18
- Site team plus Sponsor/CTU team: 15/18
- Sponsor/CTU team only: 2/18

The chart below shows how access to certain fields within the SAE report could be restricted, for example to allow only a PI or delegate to assess causality).

Figure 1. How do you restrict access to certain fields within the SAE report (e.g. to allow only a PI or delegate to assess causality)?



The survey identified 2 examples where a manual check by the trial team was used to set up access accounts at study start, providing appropriate access rights.

Responses showed that where system access is automated, the ability to restrict access to fields by user was also automated.

Half the systems surveyed have the capability to manage blinded data, in most cases a separate database/page contains the blinded data, with restricted access.

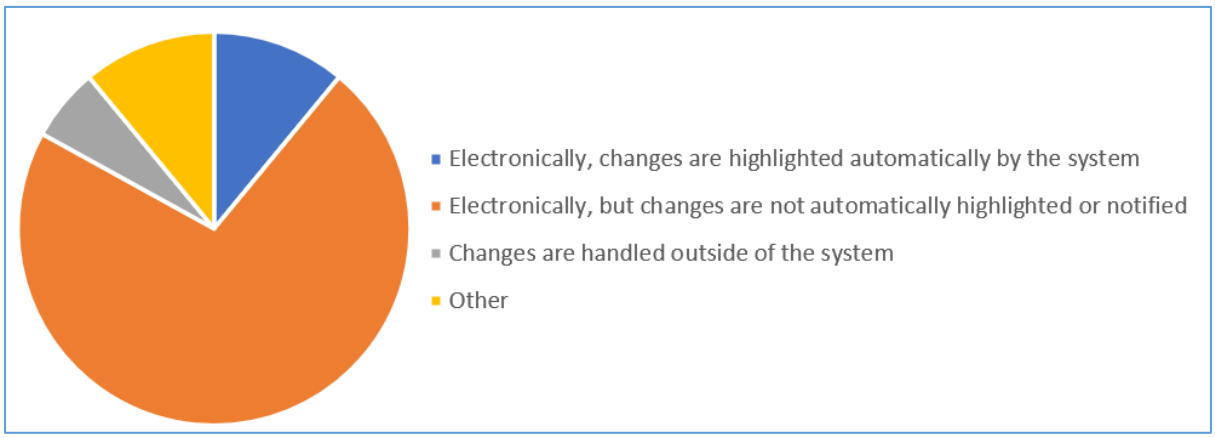
Overall, the way access to electronics systems is authorised and managed is diverse. The majority of systems are accessed by a mix of site staff and Sponsor/CTU staff.

2.2. Section 2 – Managing Information

This section of the survey gathered information on how each system managed updates, missing/inconsistent data and review/signature processes. CTUs were asked about the ability of the electronic safety reporting system to validate against other clinical databases. In some cases, the SAE form can be validated against another form within the clinical database, such as the AE form. Most comments seemed to suggest safety reporting is managed within the same database as the other CRF/EDC data, suggesting a move away from separate safety databases.

The chart below shows the majority of CTUs manage updates to the data inputted on the safety report electronically. In most cases, changes to data items are not automatically highlighted or notified by the system.

Figure 2. How does your system manage updates to the SAE report?

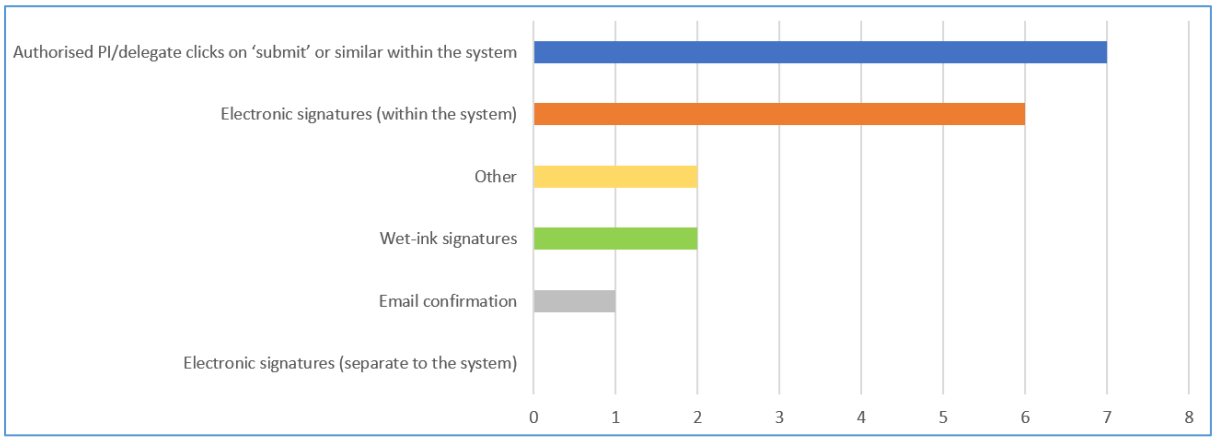


Some respondents stated that separate report function tools run checks for changes to SAE forms and email notifications are triggered to notify the trial team of the changes. Others stated that changes to event data are recorded on a follow-up SAE report form, instead of permitting changes to the initial report form.

CTUs were asked whether missing and inconsistent SAE data items were flagged automatically, identified manually, or by a mixed approach on their system. The responses were evenly mixed between the system flagging items automatically or manual checks by CTU staff. In most cases the approach was a combination of automated data validation with additional manual checks.

Most systems allowed for electronic review/sign off by the PI/delegate, either via the PI/delegate submitting the form or by adding their signature electronically (see chart below). The same applied to re-signing of SAE reports after updates. Wet ink signatures or email confirmation were accepted in a minority of cases.

Figure 3. How do you manage sign-off of SAE reports by the PI (or delegate)?



Queries on SAE reports from reviewers (e.g. CTU staff/PV team/clinical reviewer/CI) were managed either by emails to the site staff (especially for critical data items), or queries raised within the system. One respondent stated holding a weekly minuted meeting with the site.

There was a mixed response regarding the ability for the system to record SAE reviews and assessments (e.g. by the Clinical Reviewer/CI, sponsor or CTU). The majority of systems enabled reviews to be recorded (10/18). Some systems did not capture reviews or assessments, whilst others used a mixed approach, including filing emails from the reviewers in the participant record.

Most respondents stated their system could track the progress of the SAE form (initial, follow up, final). However, there was a fairly event split of automated tracking versus manual, including the use of a separate log to track progress.

Once an SAE report is complete, 67% of CTUs stated their system did not have a mechanism to prevent unauthorised changes to data within the SAE form. The remaining systems enable locking of the SAE form to prevent unauthorised changes, and any permitted changes were recorded in an audit trail.

Similarly, 67% of responses stated that their system did not have a way of recording day zero of the SAE. Systems that did allow for this manage it in a few different ways; field to record day zero, times-stamped email notification, date is automatically entered when the site submits the SAE form.

Overall, the way different systems manage information is mixed, with most having a split of automated and manual functions.

2.3. Section 3 – Notifications

This section of the survey gathered information on the automated notification functionality of each system. Of the 18 CTUs, 14/18 (83%) reported that their system could send automated notifications. Responders were asked to select those notifications that applied to their system; the most frequently selected were automated notifications for a new SAE report

(14/18 responses), follow-up SAE report (9/18 responses) and then each with 6 responses: PI sign off completed, amendments to either initial or follow up report and raising data queries. It can be concluded that the majority of systems notify the trial team of a new initial SAE report, but that subsequent/other notifications are less frequently used and those that are used, vary widely across CTUs. Where notifications were not automated, additional comments suggested the work is done manually by the majority of CTUs.

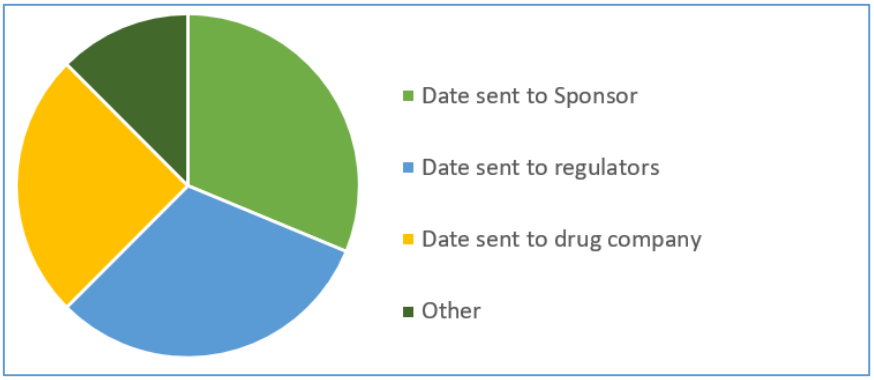
Interestingly only one responder selected that automatic notifications were received for 'onward reporting requirements' and no responders selected 'staff member completing a task which they are not delegated' nor 'follow-ups due'. Few responses were also seen for review requirements (CTU and CI). Therefore, it could be deduced that other manual methods of monitoring such requirements are being used; and thus, despite some methods of notification being electronic, manual methods are likely still heavily relied upon.

Email notifications appear to be a common method of notification.

2.4. Section 4 – Reporting Functionalities

This section of the survey collected data on the system's ability to capture onward reporting requirements, tracking the Reference Safety Information and MedDRA coding (or equivalent). Of the 18 survey responders, 7 indicated that their system could capture onward reporting requirements. Most commonly, the system captured the date the SAE was sent to the Sponsor, and Competent Authority/REC (5/7 systems).

Figure 4. Can your system collect information about onward reporting requirements?



Within the 'Other' category the following were included: date reported to collaborating international CCUs (1), and that external trackers were used for most dates (1).

In 10 of the 18 systems, it was possible to extract line listings (e.g. for Development Safety Update Reports, Data Monitoring and Ethics Committee reports, monitoring of SAE numbers, administration purposes etc). Customised safety reports were possible in a smaller proportion of the systems (7/18).

The majority of systems (13/18) were unable to track the relevant Reference Safety Information (RSI) for each reported SAE. In the systems that were able to track RSI information, it was notable that a manual step was still required (i.e. cross-checking the RSI version against the onset date of the event).

There were 5 systems (out of 18) with automated MedDRA coding built in. Of these 5 systems, 3 were RedCAP-based, and the other two were bespoke systems.

In summary, there was significant variability within the reporting functionality of systems used for SAE reporting across responders. Few systems could fully capture all information needed to fully track the SAE reporting pathway and many CTUs utilised manual trackers. There are particular deficiencies in the tracking of RSI information used to assess the expectedness of events and the inclusion of MedDRA auto-coding. While the majority of systems could be used to generate data for external use, this valuable functionality is not ubiquitous.

2.5. Section 5 – System Specification

This section of the survey gathered information on the software tool(s) used by each CTU, and whether it was separate to the main trial database along with details on the audit trail and back-up functionality. The majority of responders (16/18) stated that SAE reporting was included within the main clinical database (i.e., where CRF/EDC data is stored). The majority of comments indicated that the principal reasons for this were: ease of use, convenience, and practical reasons. For example, ensuring that all clinical information for the trial is captured in one place and ease of use by CTU teams, signatories and site staff being mentioned. Some CTUs stated that including SAE reporting in the main trial database is a logical step, whilst another mentioned it being there due to lack of other suitable software. Of interest, one of the two systems reported as external to the main trial database was designed to be independent, allowing for bespoke reports and the export of listings. It would be interesting to know if this is a limitation of integrated systems or whether the software used to create the trial database plays a role in this.

Responders were asked what type of devices their system could be used on, of the 18 responders, 11 indicated their system could be used on both desktop and mobile devices (with the remaining seven being desktop only).

Regarding the question ‘which software tool(s) is your system built in (select all that apply),’ the highest responder count was in the ‘other’ category, with most responders indicating a bespoke system (one stating InFORM). Of the options available, MACRO was the most frequently used software tool (5 responders), with OpenClinica and REDCAP (Academic and Cloud) also being used to a lesser extent (4, 3 and 3 responders respectively).

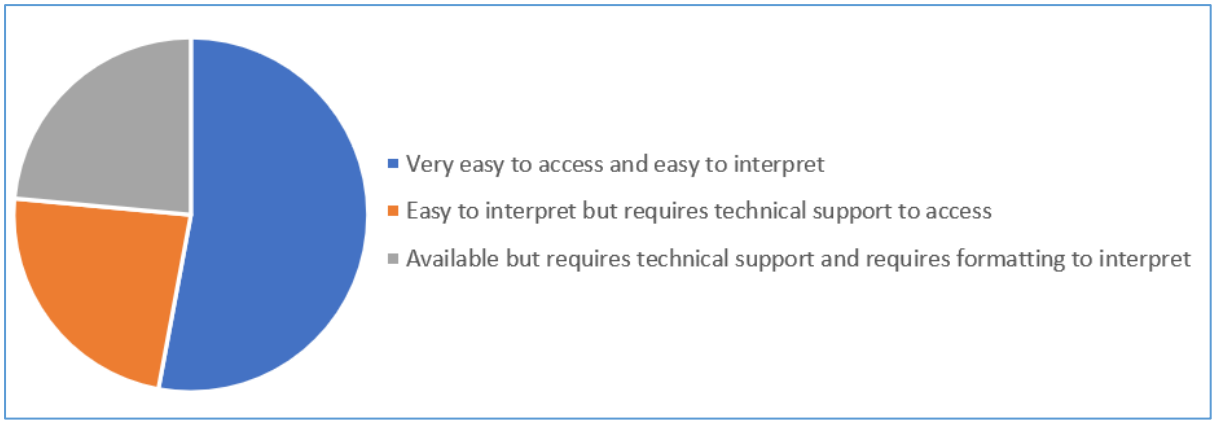
A high number of responders noted that their system, if separate from the main trial database, could not integrate with other databases, however from the additional comments it appears that these responses may have reflected those that have a system that is not separate from the database – a ‘N/A’ option was not available for this question, an oversight in the survey design, and therefore not much can be deduced from these responses unfortunately. However, there was one ‘yes’ responder who had a bespoke system that could integrate with other databases; being able to retrieve data from other trial systems.

The majority of systems had a full audit trail (94%), the responder indicating ‘no’ included comments alluding to the manual steps involved in SAE processing e.g., email queries which are not in the system and therefore not included in the recording of all activity. Thus, it seems the electronic systems themselves have audit trials, but this is lacking with the more manual elements seen alongside such systems.

Responses relating to audit trial accessibility were more varied. Over half of responders stated the audit trial is *‘very easy to access and easy to interpret,’* the rest of responders were split between *‘easy to interrupt but requires technical support to access’* and *‘available but required technical support and requires formatting to interpret.’* There were

inconsistencies in responses between CTUs using the same software to develop trial databases. For example, for MACRO responses relating to accessibility of the audit trial included two stating *'very easy…,'* one saying, *'easy to interpret but requires technical support to access'* and one that *'…required technical support and reformatting to interpret.'* This could be indicative of differences in user training or confidence rather than the software itself.

Figure 5. How accessible is the audit trail?



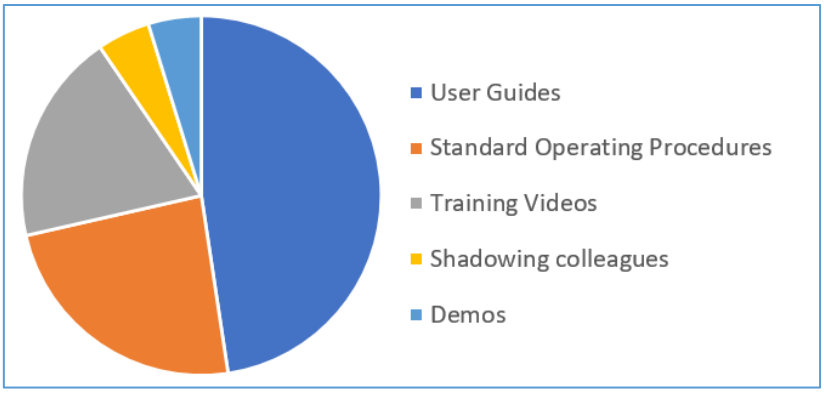
All responders noted that their system is backed up, but 89% when asked how accessible the back-ups were noted that it required technical support to access. One comment noted 'per vendor process…' and thus it may be that this accessibility is related to the vendor used rather than any limitations of the system itself.

Overall, there is variety in the software used, with many CTUs taking a bespoke approach to the development of a safety reporting system. This suggests a lack of cost effective, readily available, and widely used tools for electronic safety reporting systems for use within academic trials units. Within the software used to develop systems there is variation regarding accessibility of the audit trail. If a particular system or software could be endorsed, greater training and peer support could provide clarity with regard to ease of audit trail access and interpretation. However, this accessible audit trail is not all encompassing if parts of SAE processing are still undertaken manually.

2.6. Section 6 – Availability and Usability

This section of the survey focussed on the ease of use of the system, training and availability to other CTUs. All survey responders (18/18) found their local systems easy and intuitive for site and CTU staff to use. 7 out of 18 of the systems reported on did not require a clinical reviewer, but for those systems where a clinical reviewer required access to the system, it was felt that for 9 out of the 11 systems, it easy for the clinical reviewer to use the system. For those 2 systems where clinical review access was not straightforward, feedback was that training was required on the system as finding all the necessary information was not intuitive. 17/18 systems had training materials either already available or under development. The chart shows the format of such training materials.

Figure 6. What training materials are available for your system?



Of the five bespoke systems reportedly in use, none of the CTUs planned to make their systems available to other CTUs.

In summary, CTU and site staff are finding the systems easy to use, but in some cases finding it is harder to obtain the clinical reviewer's input. The systems in use have a broad range of training materials available or in development.

2.7. Section 7 – Development

The final section of the survey focussed on the system's development and testing specification, and the level of internal/external validation/audit that each system had undergone. For the 16 systems for which we received responses to this question, every system was developed by a multidisciplinary team of CTU staff. The multidisciplinary teams were made up of various combinations of pharmacovigilance staff, quality assurance staff, information technology (IT)/information systems (IS)/database managers, trial/data management staff and statisticians. All systems (18), with the exception of one which was built in MACRO, had been internally validated, usually by a small multidisciplinary team comprising trial/data managers, IT and pharmacovigilance teams and by investigator site staff in 1 case. 13 out of the 18 systems had not been externally validated. Of the 5 systems which had been externally validated this was through a combination of MHRA inspection (2) and one system was a commercially purchased product. Software and system change requests were generally managed by the data management/IT/IS teams within the CTU. Funding sources used to develop the systems were varied, including either funding from a single trial or multiple trials hosted at the CTU, core CTU funding, NIHR funding and Sponsor funding.

In summary, the systems were developed by multidisciplinary teams and went through internal validation processes.

3. Conclusion

The survey shows that collection of safety data via electronic safety reporting systems by academic CTUs is very much a work in progress. Off the shelf clinical databases are in use by the majority of respondents, with bespoke software solutions used to a lesser extent. Functionality of the software solutions differs significantly between CTUs with little consistency even where commercially available, off the shelf software is used to collect

safety data. Few trials units are using electronic reporting for all safety reporting activity, with many using a hybrid paper/email/electronic system to capture the SAE review process. The ability of the systems to prepare reports for regulatory or in house use differed significantly between CTUs with most lacking the ability to collect all data required to fully track an event from initial report through to clinical review and expedited reporting where applicable. Again, hybrid systems were in the majority for the tracking of SAEs for administrative or regulatory purposes.

While the majority of responding CTUs have moved onto the use of electronic collection of safety data there is little conformity between systems, and none appear to fully and efficiently meet the demands of teams responsible for safety reporting within clinical trials. There is considerable scope for the development of a system fully encapsulating these needs; particularly given the basic underlying principles of processing safety data are fundamentally fixed with distinct logic dictating how reported events are treated. In addition, the regulatory reporting requirements and associated data are also fixed and particularly suited to a fair degree of automation. While there are commercially available systems for the handling of safety data these are prohibitively expensive for academic CTUs and a more cost-effective solution must be sought if fully electronic capture of safety data is to replace the traditional paper-based model for collecting and reporting safety data.

It is important for Sponsors to consider reporting requirements when implementing systems for electronic safety reporting. There are unique challenges for safety data that do not necessarily affect the collection of other clinical data and therefore developing systems specifically for safety data is ideal, rather than the current method of retrofitting current data collection tools to collect safety data. Given safety data is largely fixed in nature and the types of reporting required are generally similar between all CTUs, standardisation should be achievable.

The survey responses raised questions surrounding demonstrability of audit trails, what is ‘best practice’ for tracking when using a combination of processing methods, availability of peer support in the use and management of systems and whether an increase in autonomy for access would be a viable route for increasing efficiency. Whilst it is apparent that manual steps are involved in managing access to electronic systems for safety reporting, the writers of this report recognise that a manual measure may remain a necessary and important step in electronic safety reporting e.g. crosschecking with a delegation log (whether that be paper or electronic).

With a move to electronic ways of processing safety events and the variety of responses seen in doing so, new questions have been raised relating to the accessibility of back-ups to databases and training and confidence gaps in database use and handling safety data held on an esystem.

Whilst out of the scope of this survey, the use of electronic systems for managing SAE reporting and its potential impact on other areas of trial work should not be negated, for example the utilisation of electronic SAE reporting in relation to improving the ease of on-site/remote monitoring.

It’s clear from the survey results that there is significant expertise in the development of electronic systems for safety reporting across the CTUs. Given the similar requirements for managing clinical trial safety data across the CTUs a suggested solution would be the creation of a collaborative working group consisting of developers, data managers, trials managers and pharmacovigilance experts from across the UK focussing on the development of a system that can meet the needs of an academic CTU. Such a project would be

dependent on the identification of a suitable funding source, but if successful the positive impacts of developing such a system on the delivery of non-commercial clinical trials within the UK would be significant.

Appendix A – Survey Questions

USE OF ONLINE SAFETY REPORTING SYSTEMS IN CLINICAL TRIALS

https://forms.office.com/r/ERv6SVg6Hz

The survey should be completed online, but the questions are listed below for reference.

How would your safety reporting system be best described?

- Fully online/electronic (paperless)
- Partially online/electronic (not completely paperless)
- Safety reporting is all done using a paper-based system (includes e-mailing and faxing) *(please skip to Final Comments section)*

What types of trial can your system accommodate? (Please check all that apply)

CTIMP (blinded)	CTIMP (open-label)
Non-CTIMP	Device trial (non-CE marked)
Blinded	Device trial (CE marked)
Device	Radiotherapy
Surgery	Other – if yes, please specify.

ACCESS

How do you manage/authorise access to your system (e.g. user registration and delegation log tasks)?

- Access is electronic, but users are checked manually
- Access is electronic and automatically checked (linked to a user management system)
- Other, please specify.

Which roles could have access to your safety reporting system? (Please check all that apply)

Research Nurse
Principal Investigator (PI)
Chief Investigator (CI) / Clinical Reviewer
Pharmacovigilance Monitor at CTU
Sponsor
Other – if yes, please specify.

How do you restrict access to certain fields within the SAE report (e.g. to allow only a PI or delegate to assess causality)?

- Access controlled by validation within the system (e.g. fields restricted based on user role)
- No restrictions but checked automatically (e.g. through audit trails run against scripts)
- No restrictions but checked manually (e.g. through audit trails or free text names filled in)
- Other, please specify.

Can your system restrict access to blinded information?

- Yes
- No
- N/A – No blinded information to be stored

MANAGING INFORMATION

Can your system validate data against other databases in any of the following ways? (Please check all that apply)

Checks start date of SAE is not pre-consent date
SAE is initiated automatically if AE of appropriate seriousness is entered in eCRF data
Checks basic identifiable data (PID, DOB, Gender etc)
Other – if yes, please specify.

How does your system manage updates to the SAE report (e.g. new information added to an SAE report)?

- Electronically, changes are highlighted automatically by the system (e.g. visual highlight or notification of change)
- Electronically, but changes are not automatically highlighted or notified
- Changes are handled outside of the system
- Other, please specify.

How do you manage missing and inconsistent data items on SAE reports (e.g. fields that are required)?

- Flagged automatically on the system (e.g. data queries, notifications via programmed checks)
- Reviewed and identified manually (includes programmes run outside of the system)
- Other, or mix of the above options – please specify.

How do you manage sign-off of SAE reports by the PI (or delegate)?

- PI/delegate clicks on ‘submit’ or similar within the system – only an authorised PI/delegate can do this
- Electronic signatures (within the system)
- Electronic signatures (separate to the system) *(please specify)*
- Wet-ink signatures *(please provide further detail)*
- Email confirmation
- Other, please specify below:

Does your system have a requirement for a Principal Investigator to review a report within a specified timeframe?

- Yes
- No

In your system, how are queries from the reviewer addressed with a site or unit?

How do you manage re-signing of SAE reports by the PI (or delegate) (e.g. following changes/updates to the SAE form)?

- Same as previous question (*how do you manage sign-off of SAE reports by the PI?*)
- In a different way, please specify.

Can your system record SAE reviews and assessments (e.g. by CI, CTU or Sponsor)?

- Yes, multiple reviews of the same event can be recorded within the system. It is easy to query specific items throughout the report
- Yes, multiple reviews of the same event can be recorded within the system. Comments must be recorded in one place (not on the data item(s) being queried)
- It is not possible to record reviews within the system
- Other, please specify.

Can your system track progress (e.g. current status (initial, follow-up, final), more information required, complete, locked)?

- Yes, automated
- Yes, manual
- No

Does your system have a mechanism to prevent unauthorised changes to completed SAE reports?

- Yes *(please describe)*
- No

In your system, do you have a way of recording Day 0 to assist with tracking SUSAR reporting due dates?

- Yes *(please describe)*
- No

NOTIFICATIONS

Can your system send automated notifications?

- No
- Yes (select all that apply):

New SAE report
Follow-up SAE report
PI Sign-off required
PI Sign-off completed
Amendments to either initial or follow up SAE reports

CI Review required
CI Review completed
CTU Review required
Missing data items
Raising data queries
Acknowledgement receipts
Staff member completing a task which they are not authorised to
Follow-ups due
Onward reporting requirements (Sponsors, CTUs, regulators)
Responses to data queries
Other – if yes, please specify.

REPORTING FUNCTIONALITIES

Can your system collect information about onward reporting requirements?

- No
- Yes (select all that apply):

Date sent to Sponsor
Date sent to regulators
Date sent to drug company
Other – if yes, please specify.

Does your system have onward reporting functionalities? (e.g. export of SAE data)

- No
- Yes (select all that apply):

Line listings for DSURs, DMECs etc.
Specific safety reports
Other, please specify.

Can your system track the relevant Reference Safety Information (RSI) for each individual SAE?

- Yes *(please describe below)*
- No
- Other, please specify.

Does your system have functionality to allow for in-built MedDRA coding?

- Yes, automated MedDRA coding
- Yes, MedDRA codes can be added manually
- Yes, both manual and automated
- No
- Other, please specify.

SYSTEM SPECIFICATIONS

Is your system built within your main trial database (i.e. where CRF data is stored)?

- Yes *(specify reasoning for this)*
- No *(specify reasoning for this)*

What types of devices can your system be used on?

Desktop only
Desktop & mobile devices (e.g. tablet/phone)
Other, please specify.

Which software tool(s) is your system built in (select all that apply):

CLINTRIAL	eClinical Suite
GeneSYS	MACRO
OpenClinica	ORACLE CLINICAL
RAVE	RedCAP Academic
RedCAP Cloud	Other, please specify.

If your system is separate to your main trial database, can it integrate with other databases?

- Yes (please describe the integrations and their purpose)
- No

Does your system have a full audit trail which records all activity?

- No
- Yes If yes, how accessible is the audit trail?

Very easy to access and easy to interpret
Easy to interpret but requires technical support to access
Available but requires technical support and requires formatting to interpret

Is your system backed up?

- No
- Yes If yes, how accessible are the back-ups?

Easily accessible
Require technical support to access

AVAILABILITY & USABILITY

Do you think your system is easy/intuitive for **site staff** to use?

- Yes
- No

Do you think your system is easy/intuitive for your **clinical reviewer** to use?

- Yes
- No
- N/A – no reviewer

Do you think your system is easy/intuitive for **CTU staff** to use?

- Yes
- No

Are training materials available for your system?

- Yes *(please detail – documents / Standard Operating Procedures / videos etc.)*
- No

Do you plan to make your system available for other CTUs to use?

- Yes *(please detail below – licensing, fees, support availability etc.)*
- No
- Other, please specify below:

DEVELOPMENT

What staff roles have been involved in the development and specification of your system?

What staff roles have been involved in the testing of your system?

Has your system been internally validated? If so, by what staff role?

- Yes *(please provide details)*
- No

Has your system been externally validated/audited?

- Yes *(please provide details)*
- No

Who manages live software / system change requests?

How is your system funded?

FINAL COMMENTS

Please include any further detail you think may be useful, for example:

- specific challenges you encounter with your current system
- any concerns regarding regulatory compliance
- any tasks which can't currently be completed electronically

And if you do not currently use an electronic system for safety reporting, please tell us about any barriers to this within your CTU.

If you would be willing for someone from this UKCRC Task & Finish Group to contact you to discuss your responses further (i.e. if further clarification would be beneficial), please provide a contact email address.

https://forms.office.com/r/ERv6SVg6Hz

Please note: all responses will be anonymised in the UKCRC Published report.