SCTO PLATFORMS

# A national survey on the use of EHR systems in clinical research

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Every day, more and more health data are captured and documented electronically instead of in stacks of printouts, as it often once was. The near future promises a full transition from paper to electronic records. This digital progress is felt far beyond the initial steps of capturing patient records, however. Health data are a fundamental building block of clinical trials. So the practices of how data are selected and collected are closely linked to the regulatory requirements of clinical trials and how these trials will be run from an operational standpoint.

## The foundations of rigour required in data collection

Recording and maintaining electronic health data that are subsequently used in clinical trials require extra

rigour. These data are regulated beyond the national regulations that normally apply to handling patient data in daily clinical practice (i.e. in doctors' practices and hospitals).

To define the core requirements of trial data, one should refer to the legally binding International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice (ICH GCP, see ICH-GCP E6 (R2), revised in 2016, and in particular its integrated addendum 4.9.0.) and to the normative reflection paper from the European Medicines Agency (EMA, see the EMA's Reflection Paper On Expectations for Electronic Source Data and Data Transcribed to Electronic Data Collection Tools in Clinical Trials, EMA/INS/GCP/454280/2010, published in June 2010).

According to ICH GCP, the sponsor or sponsor-investigator of a clinical trial and the investigator of a trial site are responsible for ensuring that trial data are attributable, legible, contemporaneous, original, accurate, and complete (sometimes referred to as ALCOAC). However, the EMA's recommendations regarding necessary, commonly recognised criteria for electronic source data offer a fuller list of characteristics. The EMA indicates that data should meet all of the above criteria as well as be consistent, enduring, and available when needed (these three additional criteria are also referred to as CEA). Using these criteria recommended by the ICH GCP and the EMA is crucial for researchers wanting to obtain a reliable pool of data that can be analysed to deliver results and potentially become the basis for further research or even new treatments for patients.

Source documents (in this case patient records) are no longer only kept as hard copies on paper, but are kept increasingly and predominantly stored as digital records. Electronic health record (EHR) systems, in which patient data are recorded and stored electronically, have been developed to meet the requirements of day-to-day clinical practice. But EHR systems do not yet always meet the highly regulated requirements of clinical research.

The following are only a few topical requirements that – while beneficial – are not always met and pose considerable practical challenges:

- Data collected should have a fully and readily available audit trail.
- Monitors' access to the health data of study patients should be restricted to only those records of patients in a specific trial.
- EHR systems should have a documented quality management system.

## Surveying the use of EHR systems in Switzerland

In early 2019, the SCTO's Regulatory Affairs Platform conducted a survey that aimed to:

- determine the extent to which EHR systems have already been implemented at Swiss study sites
- assess the current experiences with using EHR systems
- explore the needs and challenges linked to complying with regulatory requirements applicable in clinical research.

The survey was sent to staff involved in the operational conduct of clinical research in Switzerland, including study nurses, study coordinators, investigators, monitors, and project managers. The level of participation in the survey was high, with notably high participation from study nurses and coordinators: of the 91 respondents who completed the survey, 64% identified themselves as study nurses or study coordinators. Survey responses were received from various institutions across Switzerland. As the survey was not anonymised, it was possible for respondents to provide information about their hosting institutions. At least 19 different institutions (i.e. hospitals and doctors' practices) participated in the survey. Of these 19 institutions,

11 were not part of the SCTO’s network.

**The results of the survey provided a favourable impression of:**

- the extent to which EHR systems are used at Swiss hospitals and doctors’ practices conducting clinical trials
- the related challenges and needs of trial staff regarding how to make their EHR systems compliant with both GCP and data protection.

**A snapshot of survey results**

The results of the survey are summarised briefly below.

**Respondents**: In total, 91 people (n=91) completed the survey. The respondents included investigators (n= 6), study nurses or study coordinators (n=58), monitors (n=10), project managers (n= 9), other clinical staff (n=4), and those who provided no information about their role (n= 4).

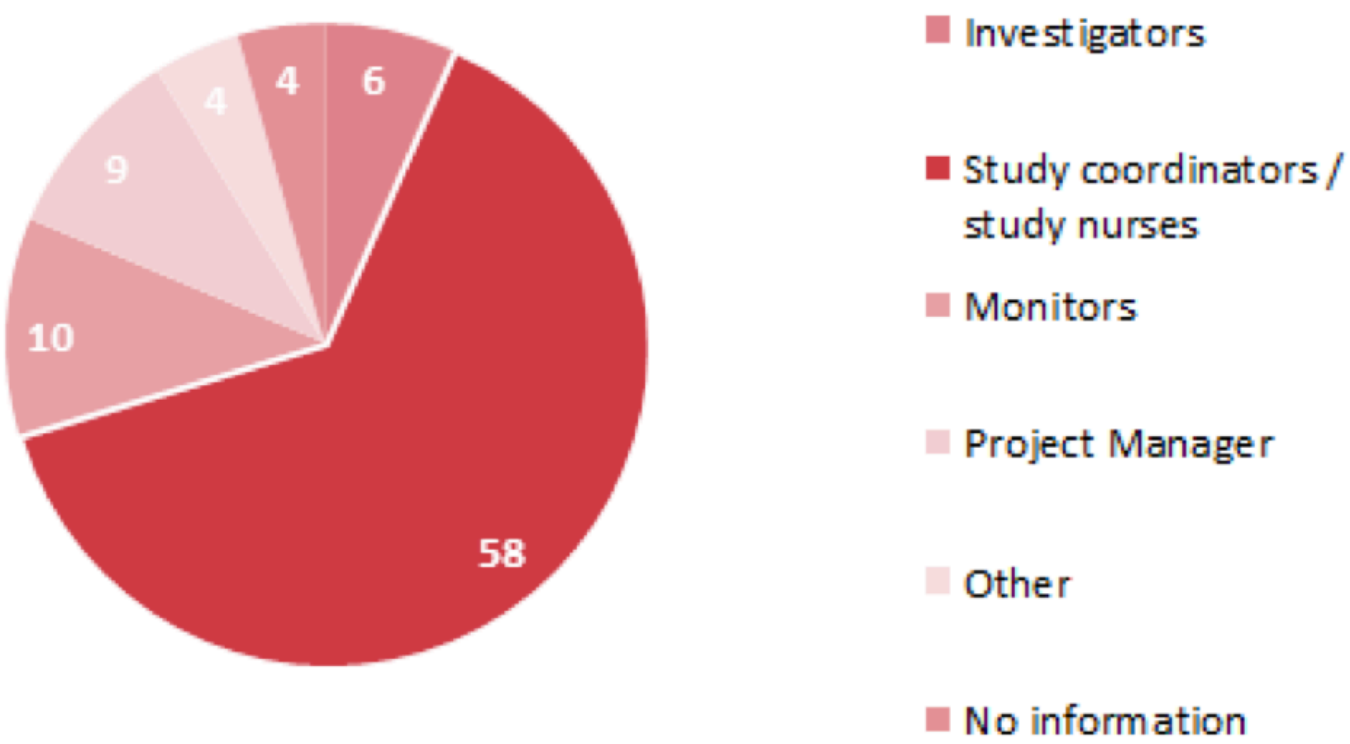


Figure 1: Overview of survey respondents categorised by their function

**Extent of use of EHR systems:** None of the institutions represented keep only paper records, although only 25% of the respondents indicated that they have made a complete changeover from paper to electronic patient records. A mix prevails, as 64% of respondents indicated that they maintain hybrid records (both paper and electronic records).

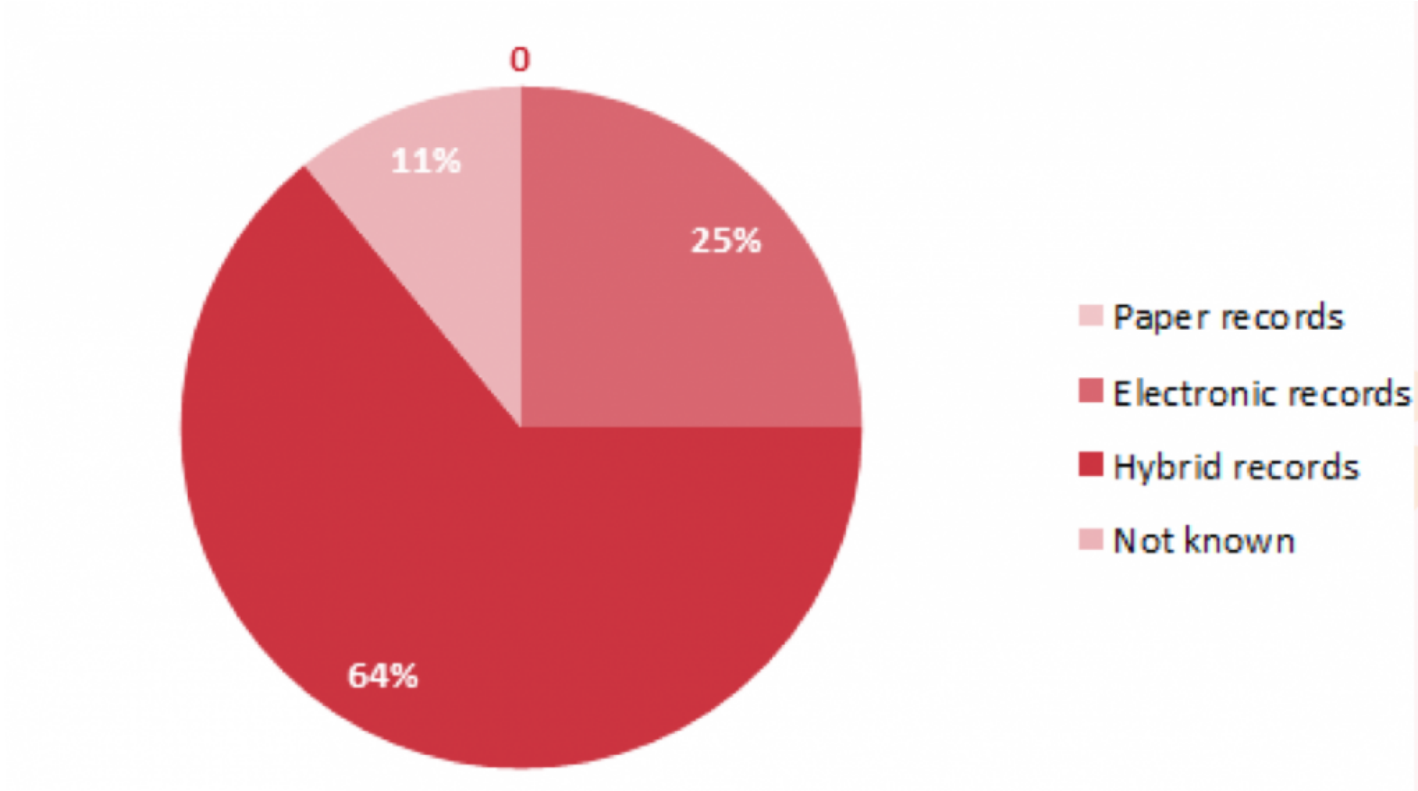


Figure 2: Overview of types of patient records kept by institutions (percentage of total)

**Daily challenges experienced by trial staff**

According to this survey, a variety of different EHR systems are currently in use. Despite this variety, respondents (n=66) cited the following common problems and challenges:

- The monitor's access to patient data is not restricted to study-specific patient data: 47.0% (confirmed by n=31/66).
- The monitor must be accompanied by the study nurse or study coordinator: 33.3% (confirmed by n=22/66).
- The monitor's access to patient data is not password restricted: 19.7% (confirmed by n=13/66).
- Patient data must be printed and signed for monitoring to take place: 48.5% (confirmed by n=32/66).
- The audit trail is incomplete: 18.2% (confirmed by n=12/66). In a further question on the audit trail, 13.2% (n=12/91) of respondents reported an incomplete or partially incomplete audit trail, and 29.7% (n=27/91) answered that they were unaware of any such audit trail. These responses suggest that the audit trail of many systems is not readily or easily accessible.
- There are repetitive questions from sponsors regarding EHR system set-up and functionality: 31.8% (confirmed by n=21/66).

**Expectations of trial staff**

Most of the respondents (66.3%) indicated that they would like to receive further regulatory information and support on handling electronic patient data collected for clinical trials, especially in the following areas:

- how to handle and generate certified copies
- how to assess the regulatory compliance of the EHR system in use for a sponsor
- written instructions for using EHR systems
- advice on what to do if regulatory obligations are not fulfilled (and on which mitigation strategies could be taken)
- the minimum requirements for using EHR systems as source data in clinical trials.

## Looking forward towards a guideline

This Swiss-wide survey on EHR systems provides a current snapshot of the common requirements of trial staff and the gaps in the use of EHR systems at trial sites. More results of the survey and an EHR system assessment form can be found on the Regulatory Affairs Platform page in the tools section. With this information collected from respondents, it may be possible to develop a common guideline on using EHR systems in a clinical research setting. Such a guideline could not only help trial staff to improve processes at their sites and institutions, but also help to establish common nationwide standards for EHR systems. A guideline document will be developed by a working group from the RA Platform and will be announced in the *RA Watch* as soon as it is available.