



Electronic Medical Records in Australia and Clinical Trials

**Briefing Document prepared by
eMedical Record Australian Pharmaceutical Industry Working Group
(A collaboration between the ARCS Clinical Quality & Compliance Education
Sub-committee and the Pharmaceutical Industry Council R&D Taskforce)**

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Professional Development for the Therapeutics Industry™



Glossary of Key Abbreviations

CRA	Clinical Research Associate
CRF	Case Report Form
ICH GCP	International Conference on Harmonisation of Good Clinical Practice
SDV	Source Data Verification
TGA	Therapeutic Goods Administration
US FDA	United States Food and Drug Administration

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The Importance of Medical Records in Clinical Trials

The Australian Therapeutic Goods Administration (TGA), among many regulatory authorities around the world, has adopted the global guideline for the conduct of clinical trials – the International Conference on Harmonisation of Good Clinical Practice (or ICH GCP). ICH GCP sets out that study sponsor monitors must review the medical records of study participants against the data captured for the trial (in the Case Report Form). This task is called Source Document Verification (SDV). Direct access to medical records is critical to demonstrate that the data captured for analysis in clinical trials are valid, in that they document the existence of a study participant, and are accurate in that they are a true record of the observations made by the investigating clinician and the diagnostic results.

If the trial data is used to support drug registration, then the medical record may also need to be directly accessed by global health authorities. If SDV cannot occur then the data will not be acceptable for registration by global health authorities (including TGA).

Sponsor and Health Authority Access to Medical Records is with Patient Consent

In addition to ensuring access to the medical records for SDV, the sponsor must comply with the privacy laws that apply in the various jurisdictions in which they undertake their research. It is a requirement of ICH GCP that the patient information sheet clearly describes not only the procedures that they will be subject to but also informs the participant that their medical records will be accessed by study staff, sponsor staff and potentially, health authorities from countries where the data is used for drug registration. It is a requirement of participation in the trial that participants consent to such access.

Using Paper and transition to Electronic Medical Records for Trial Monitoring

Historically, sponsor monitors and health authority auditors have accessed paper medical records (patient notes, print outs of laboratory reports, etc), to perform source data verification. However, there is a trend within medical practice, both in private practice and hospital based environments for data to be collected, transferred and stored electronically.

Even if the records are not made and stored on paper, the same level of access to a trial participant's electronic medical records is required for SDV. It is a requirement of hard copy reports and records used as source data that the date of their generation can be traced and any editing of, or amendment to the records tracked and the reason for changes are indicated. Using electronic medical records for clinical research introduces additional considerations and criteria that must be met in order to fulfil ICH GCP compliance and the requirements of privacy laws. As they are currently configured, most systems used to store electronic medical records do not meet the regulatory requirements of registration drug trials. This may be circumvented in some cases by the generation of paper copies of the medical records and using these as source data. However, this process is not ideal because of the potential for lost information and additional cost entailed in double handling of data.



Requirements for Electronic Medical Records

Electronic medical records must only be created stored and/or maintained using suitable, validated IT systems when used for GCP-regulated purposes. This means they must meet certain criteria, as set out in a number of guidelines and guidances such as ICH-GCP (Section 5.5.3) and US FDA “Guidance for Industry, Computerised Systems Used in Clinical Investigations” (May 2007).

1. Access to the system should be controlled by IDs and passwords and passwords kept confidential (not shared)
2. There needs to be an audit trail for capturing changes to information in the system.
3. Data in the system needs to be backed up in case of system failure or loss of data.
4. If electronic signatures are used in the system they must meet certain criteria
5. The system should be configured so that it is capable of restricting the access of various subscribers such as CRAs to **ONLY** those records for participants in the trial who have consented to have their records monitored for the purpose of the trial.

Consequences of Electronic Medical Records that do not meet ICH GCP Requirements

If the electronic medical record systems used at that trial site are not validated according to the above criteria then they will be unsuitable for use in clinical trials as the site would not comply with ICH GCP. This will mean sponsors will not be able to carry out trials at those sites.

If the system managing the electronic medical record is an otherwise suitable system but access cannot be restricted to a sponsor's study participants for CRA and auditor access, then this is a problem. This would enable the sponsor representatives and others to access the records of patients who have not given consent for their health records to be reviewed. If the electronic medical record does not allow printouts and also does not allow appropriate monitor access then the site will not be able to carry out studies in accordance with ICH GCP requirements. Sponsors will not be able to use those sites.

Australia's Global Competitiveness and Electronic Medical Records

Australia must compete with the world for global clinical trials. As electronic medical records become more commonplace in Australia, it is critical that they meet the requirements of ICH GCP and privacy requirements to allow appropriate, quick and efficient access to sponsor monitors and health authority auditors. If not, then Australia will lose clinical studies to other countries around the world



Summary of Key Questions in Regards Electronic Medical Records and Clinical Trials

The following is a summary of key questions that have been used to assess appropriateness of electronic systems for trials:

A “NO” to any of these means the system is not suitable for trials.

	Yes	No	Not Sure
1. Are there unique identifiers and passwords to access the system?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Are there measures in place to keep passwords confidential (not shared)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Does the system automatically suspend or log off a user after a specified period of inactivity?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Is access to certain functions controlled based upon the user's role (e.g., read, write, change, delete)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Is there a list of individuals authorised to access each function?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Is there an audit trail for capturing changes to information in the system?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Is the original information as well as the new information still available after the change is made? (Attach example if appropriate)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Are the audit trail entries date- and time- stamped?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Does the audit trail indicate who made a change?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Is the audit trail protected from modification by users?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Are the audit trail and other security settings protected from being turned off?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Is the data in the system backed up (either via a network connection or external hard drive, for example) in case of system failure or loss of data at an appropriate frequency	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Can this backed up data be restored?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Has the restoration of backup data been tested?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Are electronic signatures used in the system?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Are electronic signatures protected from intentional or unintentional misuse?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. When a signature is applied to a record, is it protected from cutting and pasting to other records?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Are the name of the signer and the meaning of the signature displayed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. When a signed record is altered, is the signature made invalid?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Will the sponsor CRA be able access the data for monitoring?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. Is the system capable of restricting the CRA's access to ONLY those patient records of sponsor trial participants?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Is there documentation maintained on installation and training?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. Is there documentation maintained on system maintenance and upgrades?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. Is there a policy for addressing the availability of data for a defined retention period?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



About the Pharmaceuticals Industry Council (PIC)

The Pharmaceuticals Industry Council is the peak body for Australia's pharmaceutical and biotechnology industries. It brings together the innovative, generic and biotechnology industries to represent a whole-of-sector approach to addressing opportunities and threats to investment in the sector.

The PIC was established in June 2006, following the three-year implementation of the Government-endorsed Pharmaceuticals Industry Action Agenda. The PIC aims to take forward the work of the PIAA, particularly to double Australia's share of the global pharmaceuticals industry by 2012.

The biopharmaceutical sector in Australia employs approximately 30 000 people, exports more than \$3 billion worth of medicines annually and invests more than \$500 million per year in research and development collaborations with local hospitals, universities and research organisations. The industry is a major innovative contributor to the economy, and one of the most R&D intensive industries in Australia.

For more information:
<http://www.pharmacouncil.com.au>

About ARCS:

ARCS Australia Ltd is the professional development Association supporting scientists working in the development of therapeutic products in Australia and New Zealand. ARCS was established in 1984 and is a premium provider of education services and networking opportunities for its members and stakeholders associated with the industry. ARCS has 2500 members and 11 Education Subcommittees which drive the content of seminars, training workshops and conferences covering clinical research disciplines, regulatory affairs, health economics, pharmacovigilance, medical information and medical writing.

The Clinical Quality and Compliance Education Subcommittee focuses on providing support to clinical research personnel in Australia to ensure clinical studies are conducted to the highest international standards.

For more information, visit www.arcs.com.au or call 02 8905 0829