JOINT POSITION STATEMENT:

Electronic Signatures and Clinical Trial Research Agreement execution in Australia

BACKGROUND

- The use of electronic signatures or processes to facilitate business transactions has been legal in Australia since 1999. This is embodied under the Electronic Transactions Act 1999 (as amended) and the relevant complementary State Acts[1].
- Section 10 of the Act outlines the use of electronic signatures (eSignatures[2] or Digital Signatures[3]) which are deemed equivalent to other forms of signature if the identity and intention of the person signing them can be established.
- Executing Clinical Trial Research Agreements (CTRAs)[4] using eSignatures optimises digital technology for sponsors and public health organisations and is equivalent to wet ink[5] signatures under the Act.
- Additional benefits include reduced delays for CTRA execution, reduced costs, enhanced security and the ability to accommodate Government-directed requirements and Safe Work[6] principles, by reducing the risks to staff associated with wet-ink signatures.

PURPOSE

- This paper provides guiding principles to optimise digital technology for executing CTRAs using eSignatures.

SCOPE

- This document covers CTRAs, it does not propose to cover Deeds or documents that require a witness. Advice on how to execute these documents should be sought elsewhere.

LEGISLATION AND COMMON LAW

- The method of applying the signature is not the issue, it is whether that method appropriately evidences the identity and intention of the signatory, and whether there are sufficient safeguards in relation to authenticating a document and minimising the risk of fraud.
- In Australia, the execution of CTRAs using eSignature via commonly used platforms such as Adobe Sign or DocuSign is compliant with Australian legislative requirements, underpinned by the Electronic Transactions Act 1999 (Cth)[1], when the CTRAs are signed by two Australian entities.
- According to Section 127 of the Corporations Act execution is the preferred method for a company to execute a document so that parties dealing with the company can have the benefit of the statutory assumptions in section 129 (that all relevant internal requirements of the company have been complied with and that the document is binding on the company). There are strong arguments that execution by a Corporation through a digital signature platform is capable of being a section 127 signature.

Developed by CT:IQ (Clinical Trials: Impact and Quality)

- Execution of contracts needs to comply with the proper law of the contract. In the case of CTRAs, this is the law in force in the State or Territory in which the institution is located.
- Electronic execution of the CTRA by an Australian entity is capable of being valid under common law to the extent that authorised jurisdictional Government employees may execute the CTRA for and on behalf of a medical research institution with a "wet-ink" signature, there is no legal barrier to those persons executing the CTRA with an electronic signature.
- There are no specific execution obligations relating to CTRAs or medical research trials generally which would create an obstacle to electronic execution of CTRAs.
- It is important to highlight that the basis of an enforceable contract, as it lies in common law, only requires: an offer (and acceptance of that offer); the intention of all parties to be bound to the terms of the accepted offer; consideration (i.e. the passing of money or other value for a good or service); and certainty of terms.
- A signature, e-signed or otherwise, is simply an evidentiary procedure to formalise the parties' intentions to enter into an agreement.
- For the avoidance of doubt and to increase clarity around the contract parties' intentions, authority and compliance with respect to entering a binding contract, the parties may support the e-signing of a CTRA with the following:
    - the parties communicating their expectations around execution in advance, including predetermining the email addresses of persons authorised to execute;
    - printing out the electronic document once signed to satisfy any need for a physical instrument;
    - verifying that a person has executed the electronic document by another means (such as a confirmatory phone call or email); and
    - being prepared to provide evidence of due authorisation in case the counterparty requires further assurance that the company has properly authorised execution of the document.

REGULATIONS

The Medicines Australia CTRA is capable of being validly executed by electronic signature. In particular:

- The use of eSignatures is endorsed by the Australian Clinical Trials Project Reference group (CTPRG), in its document: COVID-19: Guidance on clinical trials for institutions, HRECs, researchers and sponsors. This is a joint statement that reflects the shared views of all state and territory Departments of Health, the Therapeutic Goods Administration (TGA), National Health and Medical Research Council (NHMRC) and the CTPRG, of which all of these entities are members.
- There is no requirement in Good Clinical Practice regulations for trial documentation to use wet ink signatures.

RECOMMENDATIONS

State and Territory Government departments as well as public health institutions and sponsors should establish policies and procedures to facilitate CTRAs execution using electronic or digital signatures to reduce delays to commencing a clinical trial and costs.

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1. https://www.legislation.gov.au/Details/C2011C00445
2. Execution of a contract can also be achieved through an eSignature, completed digitally by signing a document virtually, with no contact with the physical paper.
3. A digital signature refers to an electronic signature that can be verified using a process that effectively validates and connects a signature to a specific person.
    - There are a number of different kinds of digital signatures that can be used, but in general terms an individual is allocated a "private key" which is used to "sign" an electronic document. That "private key" can only be decrypted using a specific "public key". Because the "private key" is only known by the individual to which it is allocated, anyone with the public key can be certain that it has been "signed" by that person.
    - There are a number of online platforms that can be used for the execution of documents using digital signature technologies (the most prolific are DocuSign and Adobe Sign).
    - Digital signatures used through these platforms come with the benefit of an authentication function (including date stamping and tracking) on the platform. This provides a method to authenticate the identity of the person that signed the document, but it does not eliminate all risk (for example, these platforms allocate a "private key" to nominated signatories via email – if their email address is incorrect, or is accessed by a third party, the authentication process will be undermined).
4. Where CTRA is referenced it equally applies to a Clinical Investigation Research Agreement (CIRA).
5. A wet ink signature, made by hand on a document, typically with a pen and paper assists in the authentication of a document making it difficult for a signatory to deny that they are bound by a document
6. https://www.safeworkaustralia.gov.au/covid-19-information-workplaces/other-resources/national-covid-19-safe-workplace-principles