

Impact of Electronic Signature Towards Clinical Trial Agreements

The use of electronic signature is desirable for companies nowadays as technology has growingly become an integral part of our life. Not only that, implementing it can reduce the turnaround time and ensure business efficiency. Electronic signature is defined as a set of symbols or other data in digital form attached to an electronically transmitted document as verification of the sender's intent to sign the document.¹ It is a form of technology which allows you to sign a document via online. The legal definition of it is governed under Section 5 of the Electronic Commerce Act 2006, Malaysia (ECA 2006) where it states that 'Electronic Signature' is defined as any letter, character, number, sound or other symbol or combination thereof created in electronic form adopted by a person as a signature. And pursuant to Section 7 of the ECA 2006 a contract formed in accordance with the Contracts Act 1950, Malaysia through electronic communication is valid, binding, and enforceable by and on the contracting parties. In practice, most documents can be signed by form of electronic signatures however this is usually based on the discretion of the contractual parties.

Clinical Trial Agreements can be Signed Remotely

Traditionally, Clinical Trial Agreements (CTAs) were signed by way of wet ink as this is the most common method used to execute agreements. However, the COVID-19 pandemic has taken a toll towards how normal processes are usually managed. The impact of advanced technology in the world of signatures which is known as 'E-signatures' has paved a way for CTAs to be signed in a much convenient way as implementing electronic signatures can eliminate the need for the contractual parties to physically post the documents to sites which in effect will make the whole execution process more cost-saving. Not only that, but the signing parties can also sign the CTAs anywhere and they are able to use any type of electronic devices which the electronic signature software is compatible with.

Expedite the Number of Days to Execute CTAs

Previously, it took more time for sites to sign a CTA, sometimes it could take several weeks for it to be executed. There are many possible factors which could affect the delay however the primary factor of it could be that the contractual parties are in different locations, so it takes a long time to complete the execution process as the CTAs must be posted to different places. However, with the implementation of electronic signature, the agreement can be signed promptly, and this could also avoid the risk of the agreements being lost during delivery as lost paper documents necessitate starting the signing process over again and this may increase the chance of legal liability.² In results, this could improve the start-up timeline of the CTAs which could be a driving factor for sponsors to do more clinical trials.

Minimise the Risk of Unauthorised Signing and Error in CTAs Execution Process

Utilising electronic signature in CTAs would help to minimise the risk

of unauthorised execution of CTAs, especially when an electronic signature platform or software are used. This is because, most of electronic signature platform offers multiple options to verify the signatory's identity before they can sign the agreement, for example the signatory would have to enter a one-time passcode sent via text message or insert one time passcode provided by sender.

Besides that, this electronic signature platform provides certificate of completion of signatory, and they have an encryption software that able to verify the signatory's identity and provides an audit trail which is a digital log that archives when and where a document was viewed, signed and by whom it was signed³ with real date and time stamp captured including the IP address of the signatory. This helps to verify the signature made in the CTAs where we could trace it back to the signatory and further this audit trail capability provides secure verification to fight against fraud as it is much harder to forge the signature since it can easily track the user IP address. Thus, this increased the evidential weight to the electronic signature process.

Further, through this electronic signature's platform, which can automatically detect even a minor altering,⁴ we could easily identify and detect if there are any changes made by any of the parties prior to the signing as there is a record for any changes made to the agreement during or after signing.

Besides that, through the electronic signature platform, it helps us to identify any error made in signing of the agreement for example, it can detect when the signatory did not sign on the required intended part, inadvertently missed any required signature or even when it comes to the duplication of signature.⁵ From this setting, we would be able to avoid any negligence or human error in the signing process and this will prevent the parties from having to send or post the CTAs again for re execution due to such error. This proved that using electronic signature will help to lessen and reduce the dispute arise concerning the authenticity and error in the execution process.

Maintain the Confidentiality of CTAs

Utilising electronic signature in the execution of CTAs is safe and secure as it provides a stringent level of security in order to maintain the confidentiality of data. Most electronic signatures platform use world-class security software and hardware to protect the physical integrity of electronic signature, all associated computer systems and networks that process customer data.⁶

This electronic signature platform comes with built in security protocols implemented in order for the parties to securely send, receive, store the electronic agreements and safeguards the data that are stored in their systems.⁷ This built-in security protocol able to maintain the confidentiality of information in the CTAs. Moreover, most of the electronic signature software for example DocuSign is in compliance with applicable industry standards, laws, and regulations that governs the digital transaction and electronic signatures which



includes ISO 27001:2013, an internationally recognised specification for an Information Security Management System.⁸

Better Recordkeeping of CTAs

By practising electronic signature, a better record management can be achieved. First of all, we are all aware that not every business has adequate storage space, and because working from home has become the norm, not everyone may have access to physical copies of the executed CTAs. Hospitals are also dealing with the same storage problem, particularly in government hospitals where patients take up a lot of space. Additionally, it is quite common in today's business world, particularly in large multinational pharmaceutical companies, for the contract manager or legal counsel to be located overseas; therefore, by using an electronic signature, the contract manager or the legal counsel would have quick access to the document in question. As such, with having electronic signature for the CTAs the same can be stored in common folder or shared drive where people who have the right to access can do so anytime and anywhere, they wish to. However, it should be highlighted that the record of the electronically signed CTAs should be made at the moment of the transaction or incident to which it pertains, or shortly thereafter, by people with first-hand knowledge of the facts, or using tools that are typically used by the company or organization to accomplish the transaction.

Secondly, because electronic storage is more durable, it can assure that the CTAs' signatures remain visible and traceable for many years to come. This is due to the fact that storing physical copies may cause the wet ink signature to fade over time, preventing parties from exercising their rights when the time comes. Some clinical trials can last for several years, and some claims can be filed by a claimant even after the clinical experiment has physically ceased. Physical wet ink copies may potentially be lost in the event of a fire, flood, earthquake, or other uncontrollable force majeure event.

Thirdly, electronic storage of the electronically signed CTAs can aid in document verification. The electronically signed document will include a signature certificate that identifies the signatory, verifies the legitimacy of the digitised signature, and specifies the exact date and time the signatories signed the agreement.⁹ With this, the integrity of the record is being complete and consistent provided always that the electronic storage via shared folder, OneDrive or any company's platform are made timely as mentioned above.

Conclusion

It is crystal clear that electronic signature practices will certainly benefit CTA parties. Accelerated timelines for completing CTAs execution will allow parties to start clinical trials as soon as possible, wherever they wish, without undue delay. Electronic signatures reduce the risk of losing physical documents or error in signing,

and the confidentiality of contracts is protected by the practice of electronic signatures. In terms of recordkeeping, since the CTA is a very important legal document in clinical trials, an electronic record of the CTA with an electronic signature is a better choice.

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