



## Improving eTMF timeliness, completeness & consistency

trialwiseSCAN is the first vendor agnostic, mobile document scanning & indexing solution for the clinical trial industry. It is designed to reduce the bottlenecks commonly associated with eTMF filing, by automating the processes that digitize, index, and transfer paper documents from site to eTMF. The streamlined approach helps to drive greater efficiency, and delivers not only speed, but also the control required to help maintain inspection readiness.

### One mobile scanning solution for all your eTMFs

trialwiseSCAN is eTMF vendor agnostic.

trialwiseSCAN uses a phone's camera to image documents. Images are converted to pdfA files which can be indexed and exported or emailed to an eTMF. (See our whitepaper on pdfA for further information about pdfA ).

All document processing is done on-device. While on the device, documents and data remain protected by biometric login. Imaged documents and data are siloed and excluded from backup procedures to prevent inadvertent data leakage and are never diverted to external servers. (See our whitepaper on Security for further details).

### Validation Controls for Compliance

Trialwise has implemented CFR part 11 controls to validate each release of trialwiseSCAN to ensure compliance against specifications for file structure, naming conventions and metadata application. (See our whitepaper on 21CFR part 11 controls for further details)

trialwiseSCAN enables metadata to be defined and consistently applied to documents at the point of capture.

Site, Country, and Trial Level Metadata is entered once to reduce redundant data entry and manual handling. Data is siloed on-device within the app. Metadata can be entered either by the user or by system administrators.



## Default Settings

<p><b>TMF Reference Model</b></p>	<p>TMF Reference Model Version 3.1.0 (reference <a href="https://tmfrefmodel.com">https://tmfrefmodel.com</a>)</p>
<p><b>Naming Convention</b></p>	<p><b>Long Form</b><sup>^</sup> ProtocolNumber~Country~SiteNumber~ (~PersonSurname~FirstName)~ArtifactNumber~ArtifactName~Date~ DateType~DocumentID</p> <p><b>Short Form</b> (~PersonSurname~FirstName)~ArtifactName ~Date~DateType~DocumentID</p>
<p><b>Editable Metadata</b> (on-device)</p>	<p>Trial Name* Sponsor Name Sponsor Code Protocol Number* Other Trial Code Country* Site Name* Site Number* PI First Name* PI Surname*</p>
<p><b>System Requirements</b></p>	<p>iPhone (IOS 11.0 or later)</p>

<sup>^</sup>Manage preferences for date format, delimiters(~) and documentID under folder settings

\*Fields used in filename generation.



trialwiseSCAN is a CFR part 11 compliant vendor agnostic document scanning application, that helps you improve eTMF timeliness and quality by automating the processes that digitize, index, and transfer paper documents from site to eTMF.

[www.trialwise.com.au](http://www.trialwise.com.au)

