

TMF Futures Keeping Data Alive



arkivum
Bringing archived data to life

Arkivum's inaugural TMF survey, 'TMF Futures: Keeping Data Alive', was conducted in July 2020, against the backdrop of COVID-19, and is built around the insights and experiences of over 200 life sciences professionals.

The survey confirms that many organisations – CROs, sponsors (pharmaceutical and biotech companies), investigators and vendors – have made great strides in modernising the clinical trial process.

40% (comprising 48% of CROs and 38% of sponsors among survey respondents) have transitioned to purpose-built eTMF applications compared to 25% in 2015 ⁽²⁾, but challenges still remain.

The COVID-19 challenge

The COVID-19 crisis placed additional pressure on an industry which is often challenged by a lack of interoperability between eClinical systems.



Measures taken in the face of COVID-19 have presented an opportunity to accelerate the adoption of digital technology:

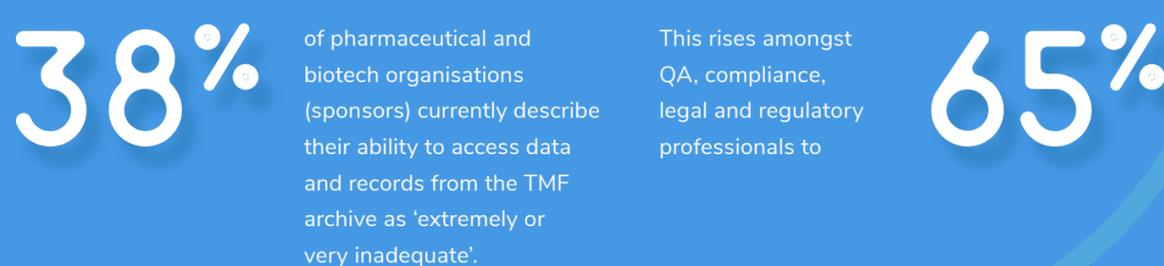


Stakeholders in clinical trials will benefit from surmounting the current challenges of interoperability and deficiencies in data management:



The eTMF has become the industry standard in the creation of the TMF, but a genuinely fit-for-purpose digital archive (which adheres to the FAIR data principles, Findable/Accessible/ Interoperable/Reusable) is often elusive:

Sponsors (36%) and CROs (48%) are moving to the adoption of purpose-built eTMF applications to manage clinical documents and store them in an archive in a bid to achieve continuous inspection-readiness,



TMF data extends beyond the immediate regulatory and compliance concerns of a clinical trial. Sponsors cite the role that TMF data plays in:



The ability to prove the what, who, why, how and when in relation to clinical research information is critical.

Russell Joyce, Director & Principal Consultant, Heath Barrowcliff Consulting Ltd & Member of the TMF Reference Model Steering Committee

(2) Veeva 2015 Paperless TMF Survey: Annual Report, <https://www.veeva.com/jp/wp-content/uploads/2015/09/2015-Paperless-TMF-Survey-Report.pdf>