## THE STATE OF TRIAL MASTER FILES: 2015 SURVEY RESULTS

In both a paper and electronic Trial Master File (TMF) environment, massive challenges delay the successful development, management and monitoring of an inspection-ready TMF. In this infographic we reveal the recent results of the Trial Master Files Europe 2015 survey conducted by Pharma IQ to gain a better understanding of how companies are planning to advance their TMF system and ensure inspector readiness in the next 12 months. Find out what are the biggest challenges surrounding the implementation of an electronic trial master file (eTMF) system and the most popular methods of exchange TMF documents with external

parties, plus investment levels and priorities for the next year.

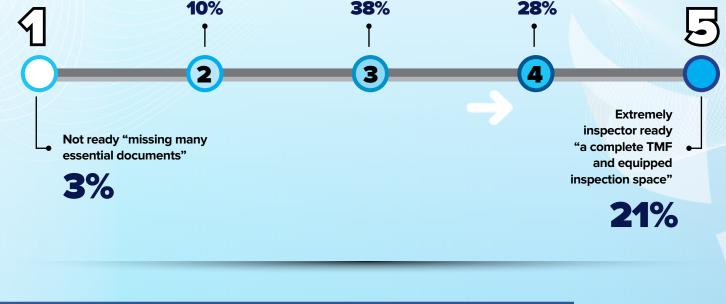
WHAT AREA(S) ARE YOU MOST FOCUSED ON IMPROVING WITH REGARDS TO YOUR TMF IN THE NEXT 12 MONTHS?



**LEVEL OF 'INSPECTOR READINESS'?** 

**▲** MONTHS, HOW WOULD YOU RATE YOUR

FROM YOUR INSPECTIONS IN THE LAST 12



50% 0% 10% 20%

**LOOKING TO INCREASE INVESTMENT?** 

IN THE NEXT 12 MONTHS HOW MUCH ARE YOU











With IRBS/

**IECs** 

With investigator



With regulatory

authorities

60%+

**CRO** sites 39% 74% 55% **Paper Post** 

Between sponsor/

Cloud	0	67%	33%	22%	22%
DMS (Document Management System)		<b>72</b> %	28%	22%	28%
eTMF Application		88%	38%	12%	25%

## **eTMF** Content management Internal file share Not applicable (using paper-based TMF) application platform system 35% 28% 4% 0%



Updating internal

equipment



Speed in study start up 48%

Cost reduction after implementation 41%

Increased operational efficiency **59%** Improved inspection readiness 63%

Easier collaboration with external parties 59% Enhanced visibility and higher TMF quality 59%

MOST RECENTLY?







strategies

for change

management

Cloud based

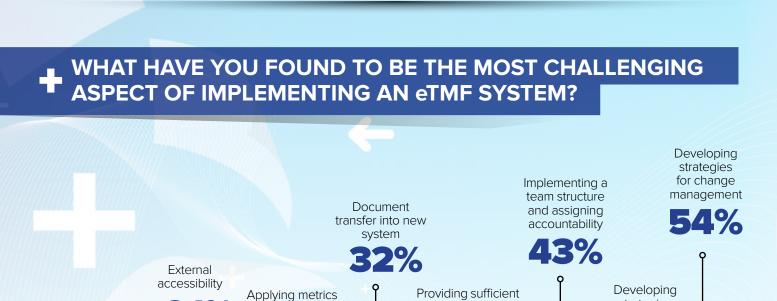
system

Real-time document tracking 70% Centralised documentation 74%

to define and

measure eTMF

health

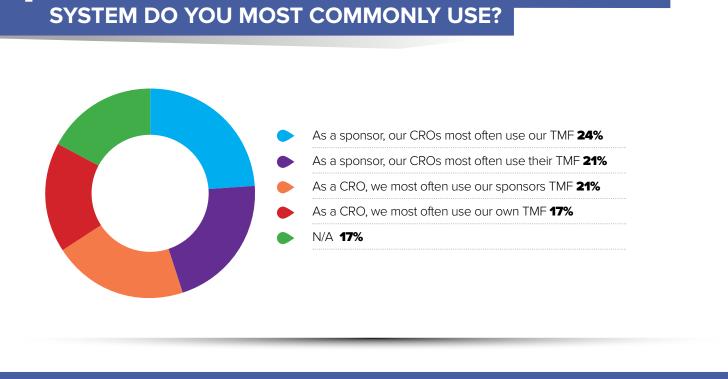


training and

providing ongoing

user support

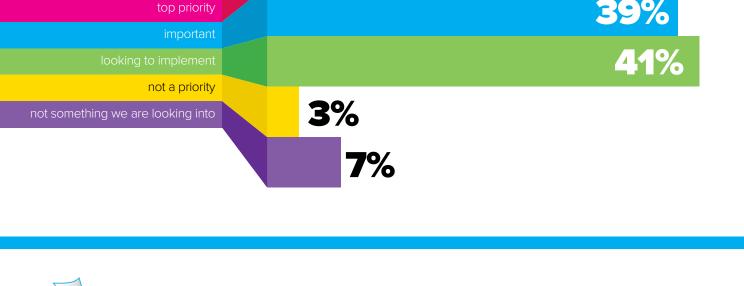
**OUTSOURCING HAS BECOME A COST-EFFECTIVE RESOURCE +** STRATEGY. WHETHER A SPONSOR OR CRO, WHOSE TMF



10%

A PRIORITY FOR YOU IN THE COMING 12 MONTHS?

IS IMPLEMENTING AND IMPROVING A METRICS PROGRAMME





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TRIAL MASTER FILES