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)

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

system and the most popular methods of exchange TMF documents with external

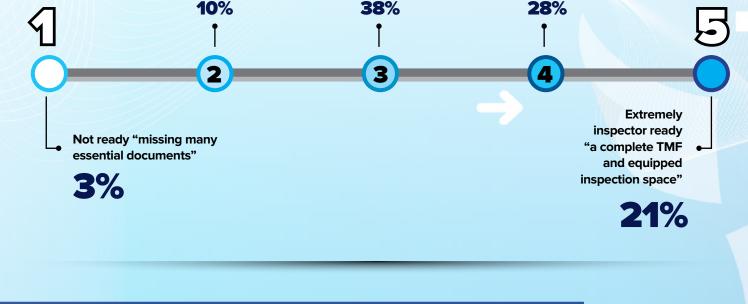
WHAT AREA(S) ARE YOU MOST FOCUSED ON IMPROVING WITH REGARDS TO YOUR TMF IN THE NEXT 12 MONTHS?



LEVEL OF 'INSPECTOR READINESS'?

▲ MONTHS, HOW WOULD YOU RATE YOUR

FROM YOUR INSPECTIONS IN THE LAST 12



0% 10% 20% **50%**

LOOKING TO INCREASE INVESTMENT?

IN THE NEXT 12 MONTHS HOW MUCH ARE YOU



Between sponsor/

With investigator

With IRBS/

IECs

CRO sites **20**% **7/1**% **55% Paper Post**

| Cloud | 0 | 53 % 67 % | 53% 33% | 33 % 22 % | 33% 22% |
|--|---|-------------------------|----------------|-------------------------|------------|
| DMS (Document Management System) | | 72 % | 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% Real-time document tracking 70%

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

MOST RECENTLY?







strategies

for change

management

Cloud based

system

60%+

With regulatory

authorities

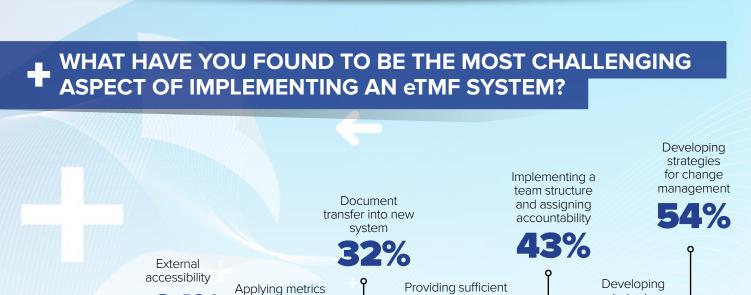
70%

Centralised documentation 74%

to define and

measure eTMF

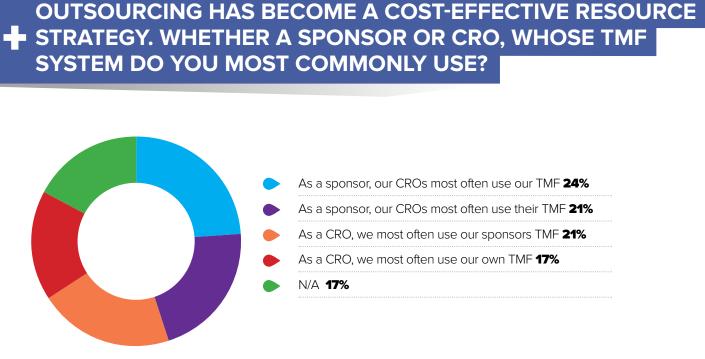
health



training and

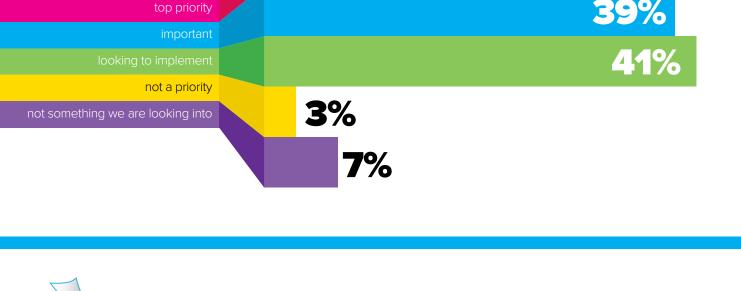
providing ongoing

user support



IS IMPLEMENTING AND IMPROVING A METRICS PROGRAMME A PRIORITY FOR YOU IN THE COMING 12 MONTHS?

10%





An Unparalleled Industry Platform Building Best Practices to **Advance Your TMF and Guarantee Compliance**

Don't miss this 100% case study and discussion based event running in Barcelona from the 7th to 9th September 2015.