

TMF Reference Model

Results of 2013 TMF Survey #3

September 2013

Fran Ross

TMF Survey Sub-team

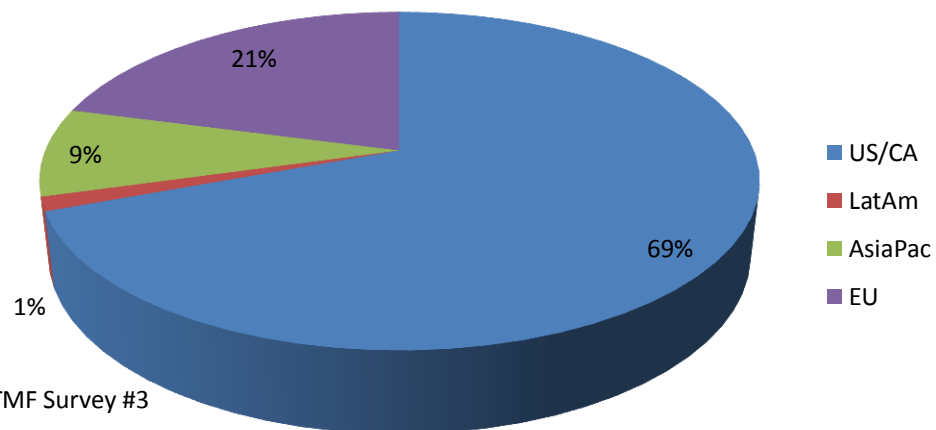
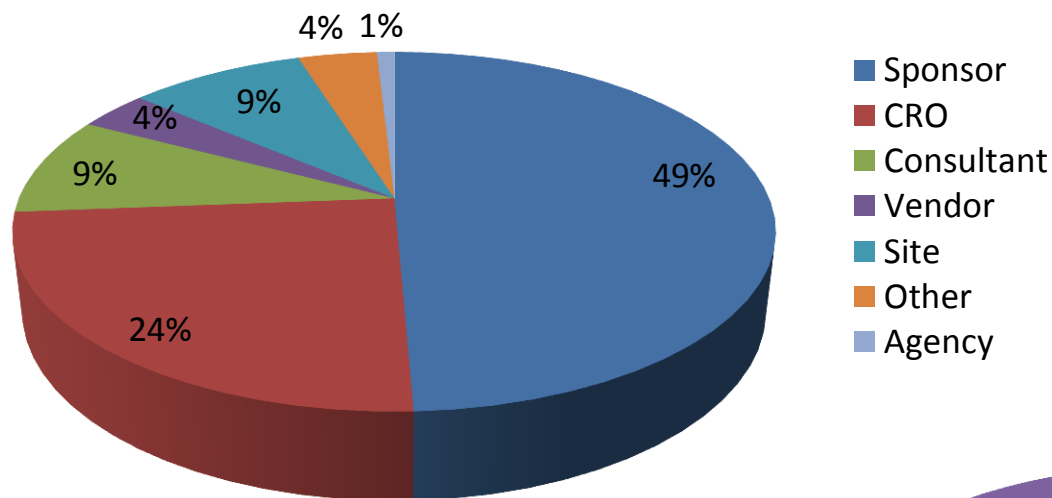
Trial Master File (TMF) Survey Background

- TMF Survey purpose: industry-wide, gather insight into quality, cost and effectiveness drivers of TMF management, including:
 - Knowledge and use of TMF Reference Model
 - Changes in TMF management and processes
 - Impacts of electronic TMF and e-Investigator Site File
- Data for 2013 Survey #3 was collected in April and May of 2013
 - Previous surveys were conducted in 2010 and 2012
- The survey sub-team will reconvene for work on the fourth TMF Survey in Q114. Your feedback, insight and participation are enthusiastically welcomed.

The TMF Survey sub-team and the Trial Master File Reference Model (TMF RM) initiative is a subgroup of the Document and Records Management SIAC of the Drug Information Association

Respondents organization types and locations

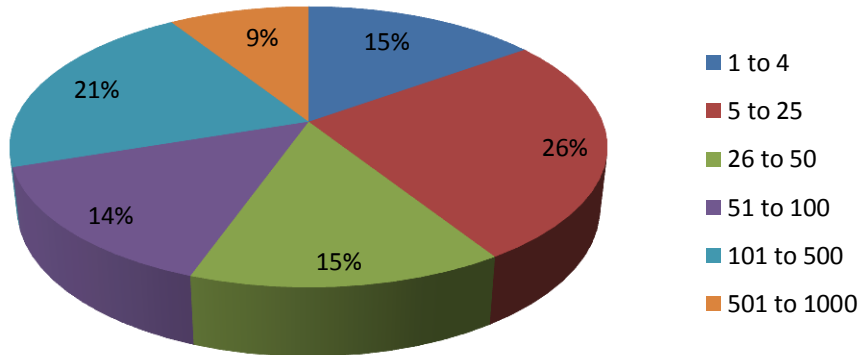
- Majority of respondents from life science trial sponsors (49%)
- Most responders US / Canada based (69%)



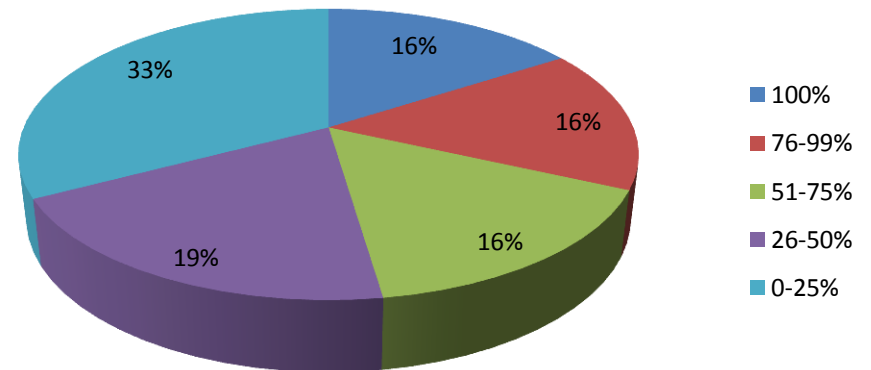
Total numbers of trials and % trials outsourced

- There were a record number of 225 respondents in 2013
- Respondents well distributed in trial size, and outsourcing models

Numbers of active trials

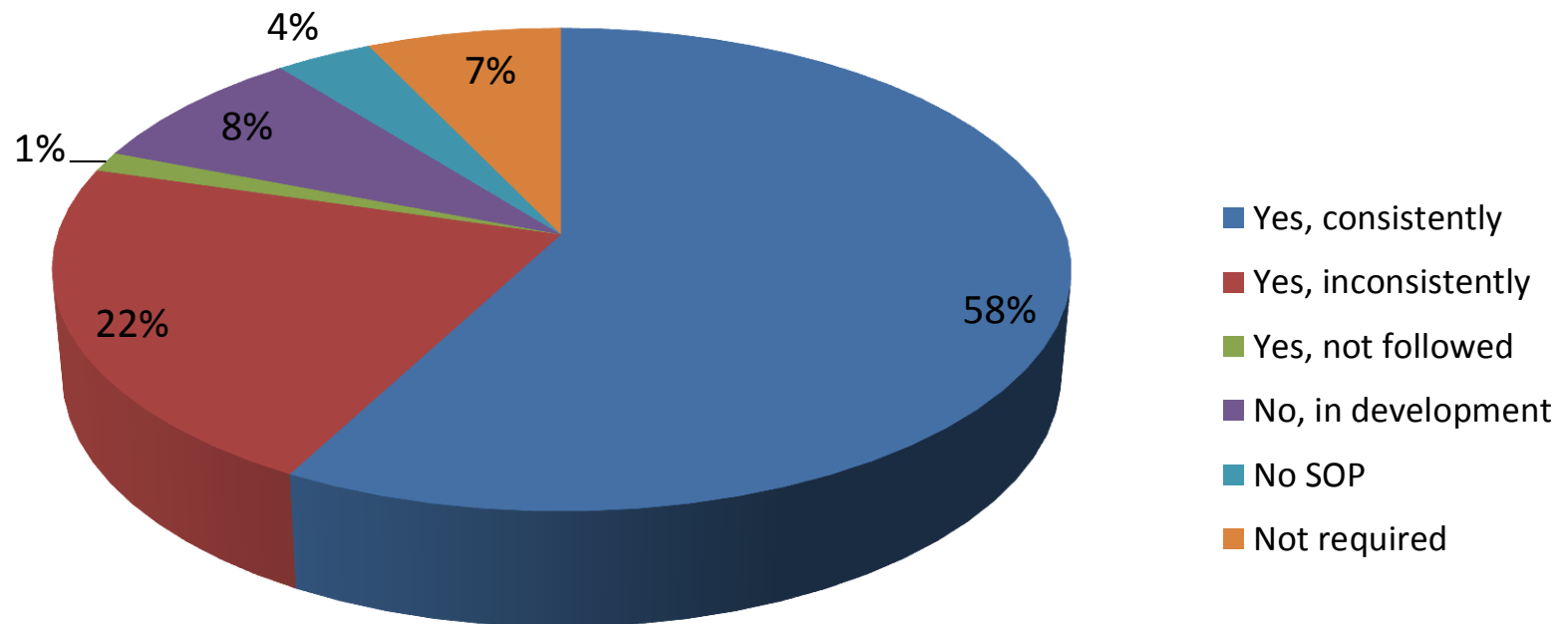


% Trials Outsourced to CRO



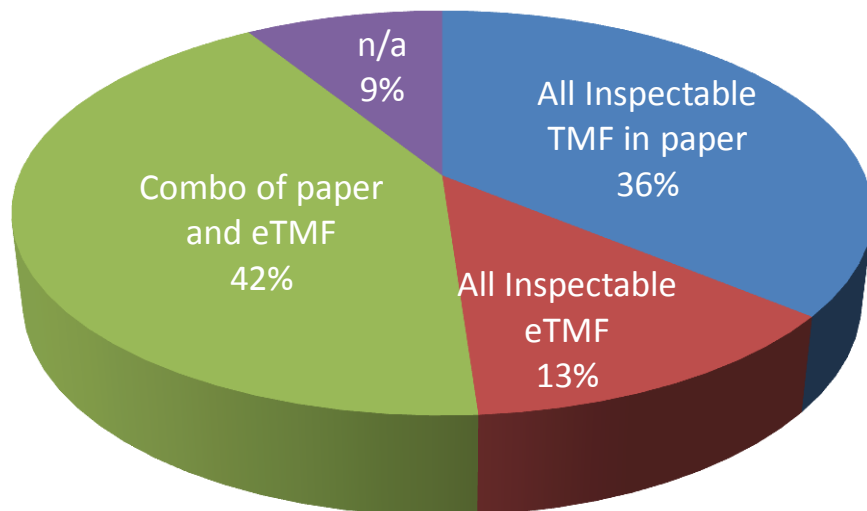
TMF SOP Adherence

Does your organization have and follow a TMF/ISF SOP?

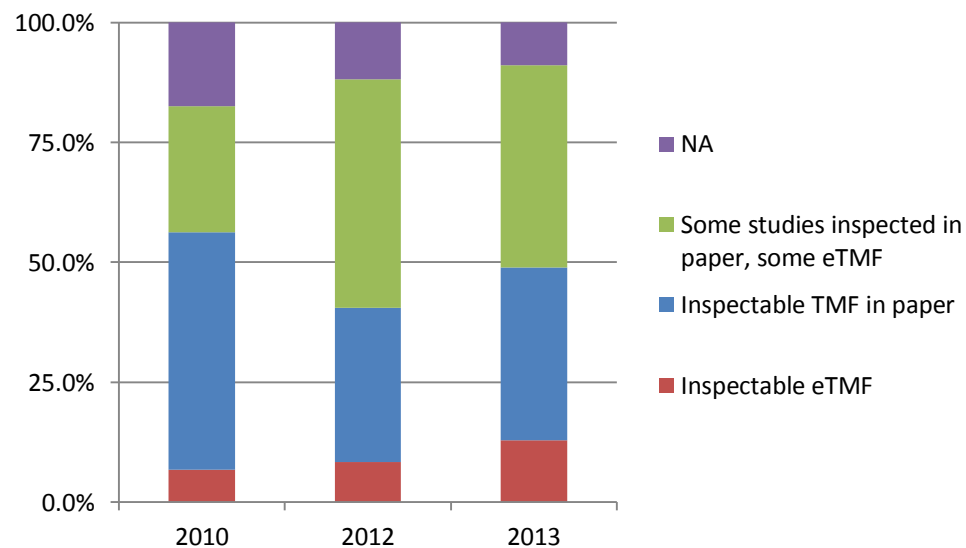


Paper and electronic TMF file of record

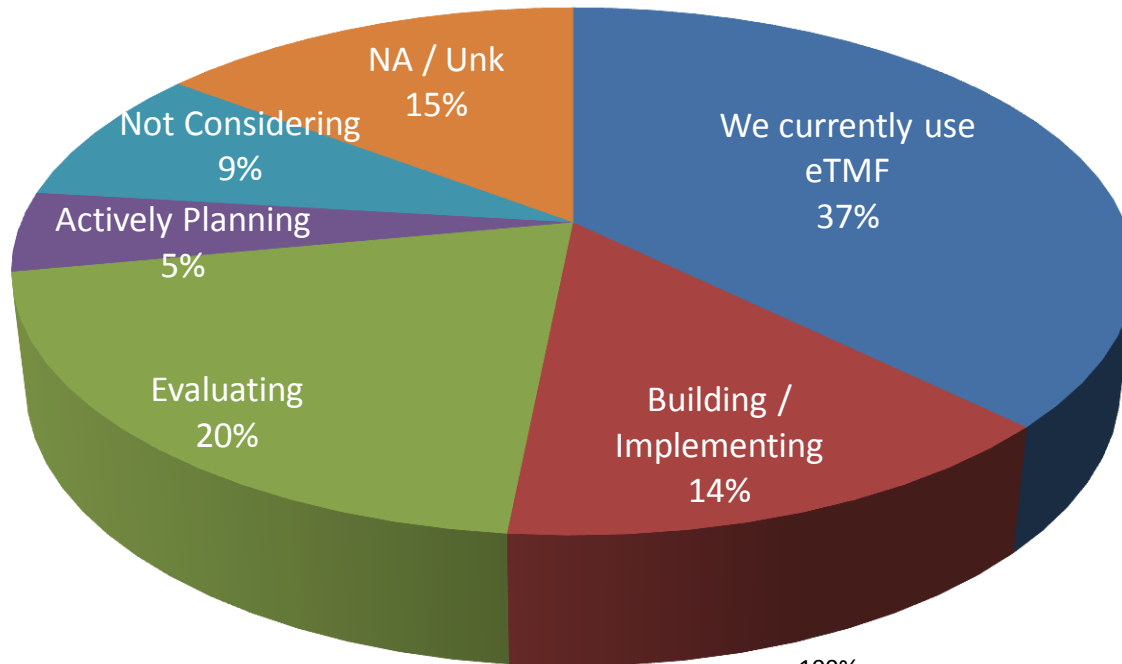
What format is your TMF file of record?



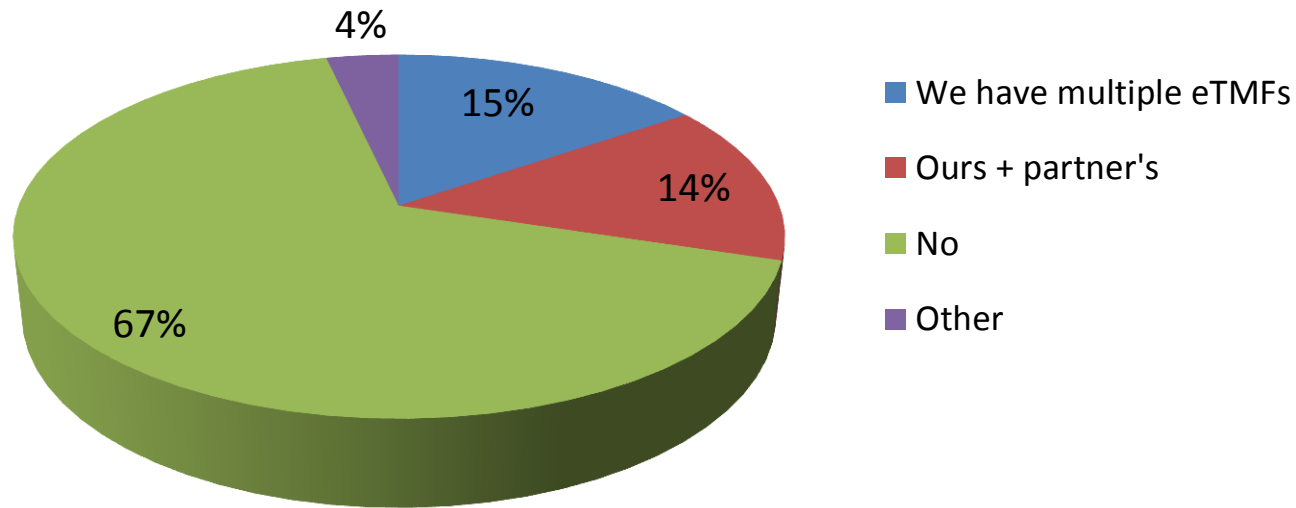
Steady, incremental growth in eTMF



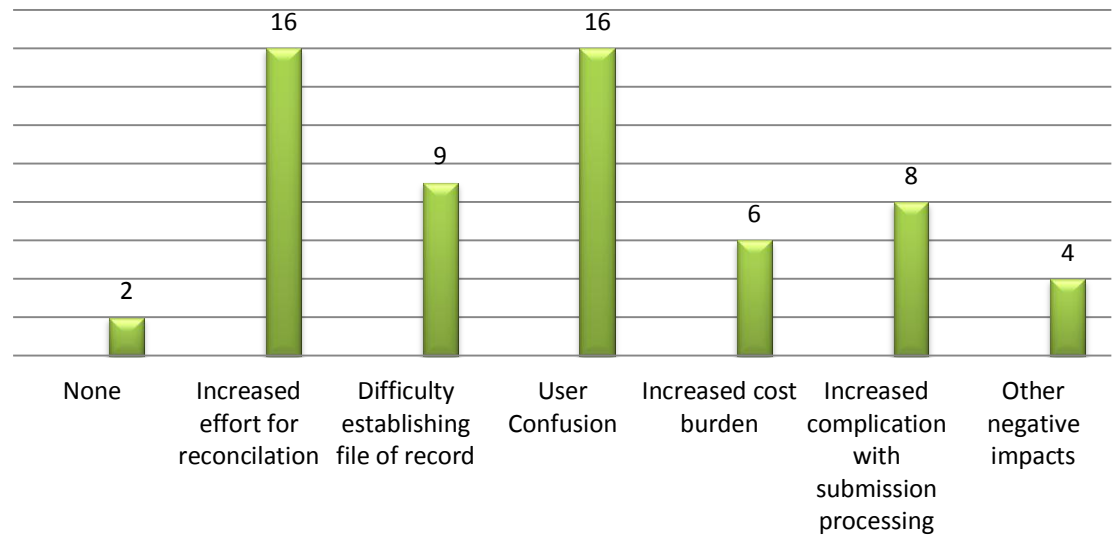
eTMF status



More than one eTMF?

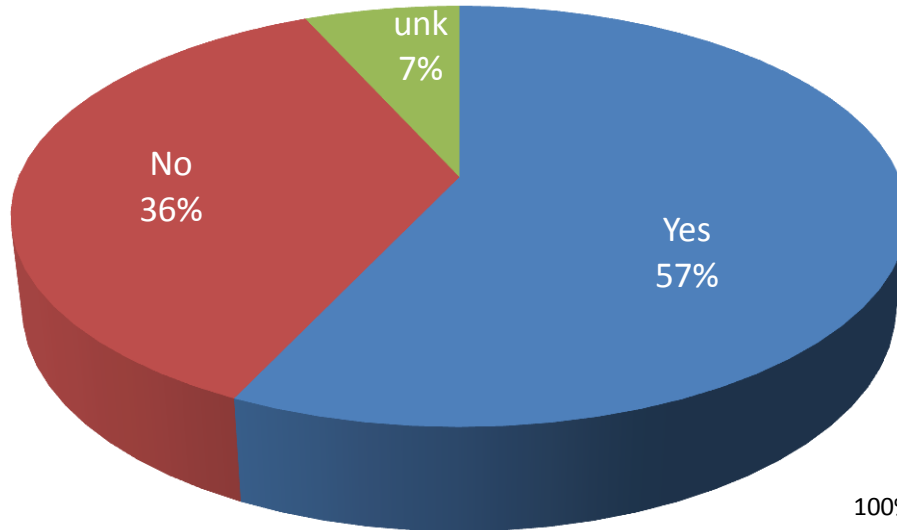


Issues with more than one eTMF

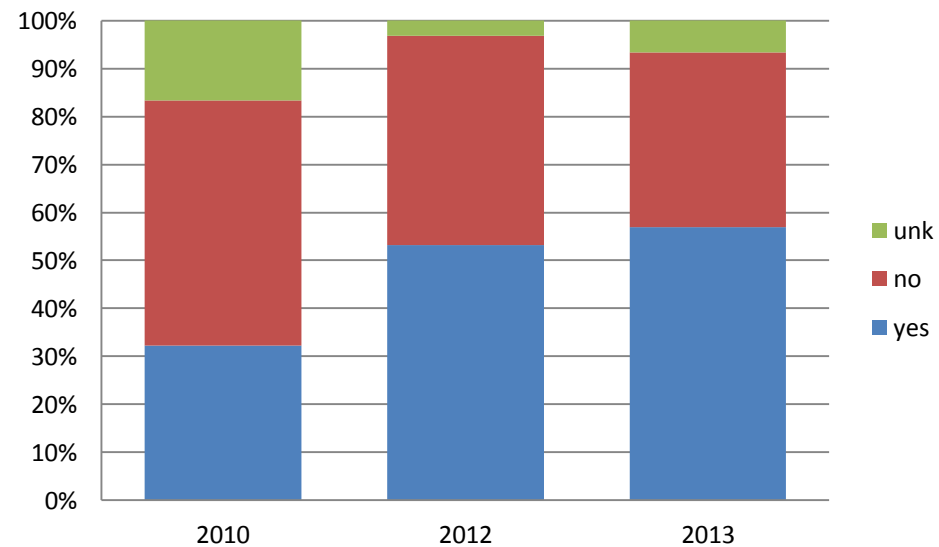


Reference Model Uptake

Is your organization using the TMF Reference Model?

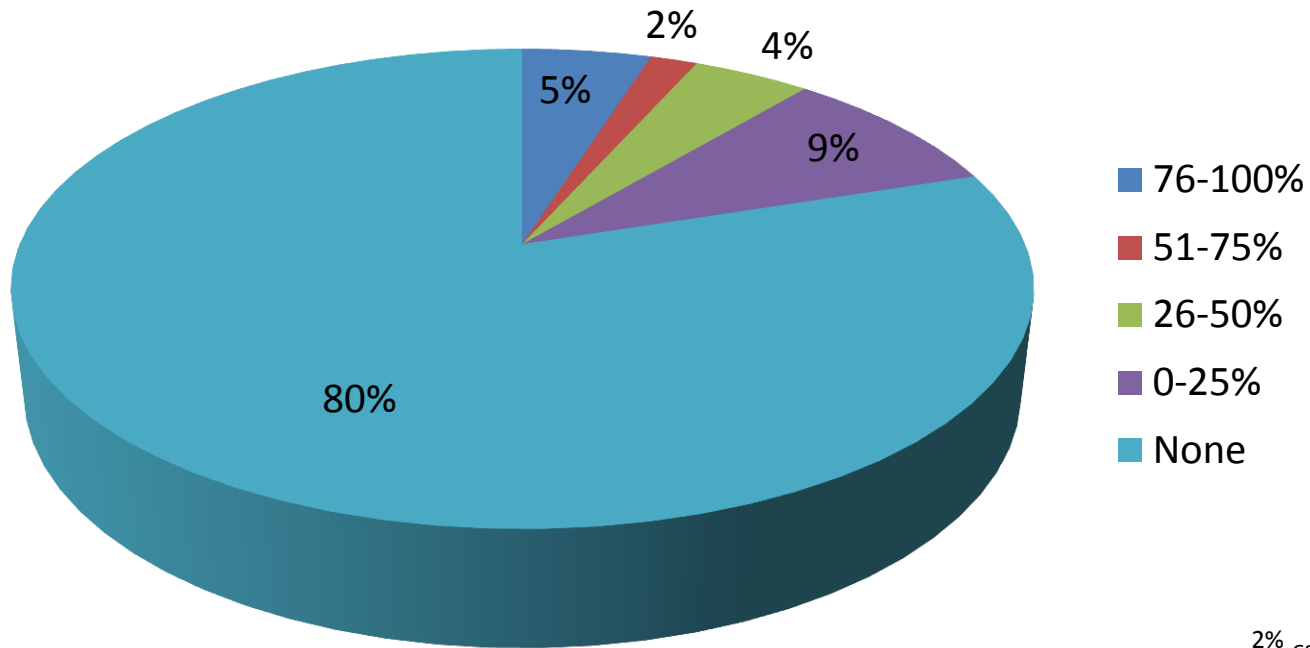


Model uptake continues to rise

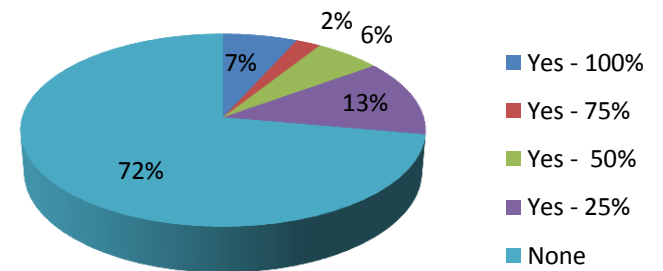


Electronic Investigator Site Files

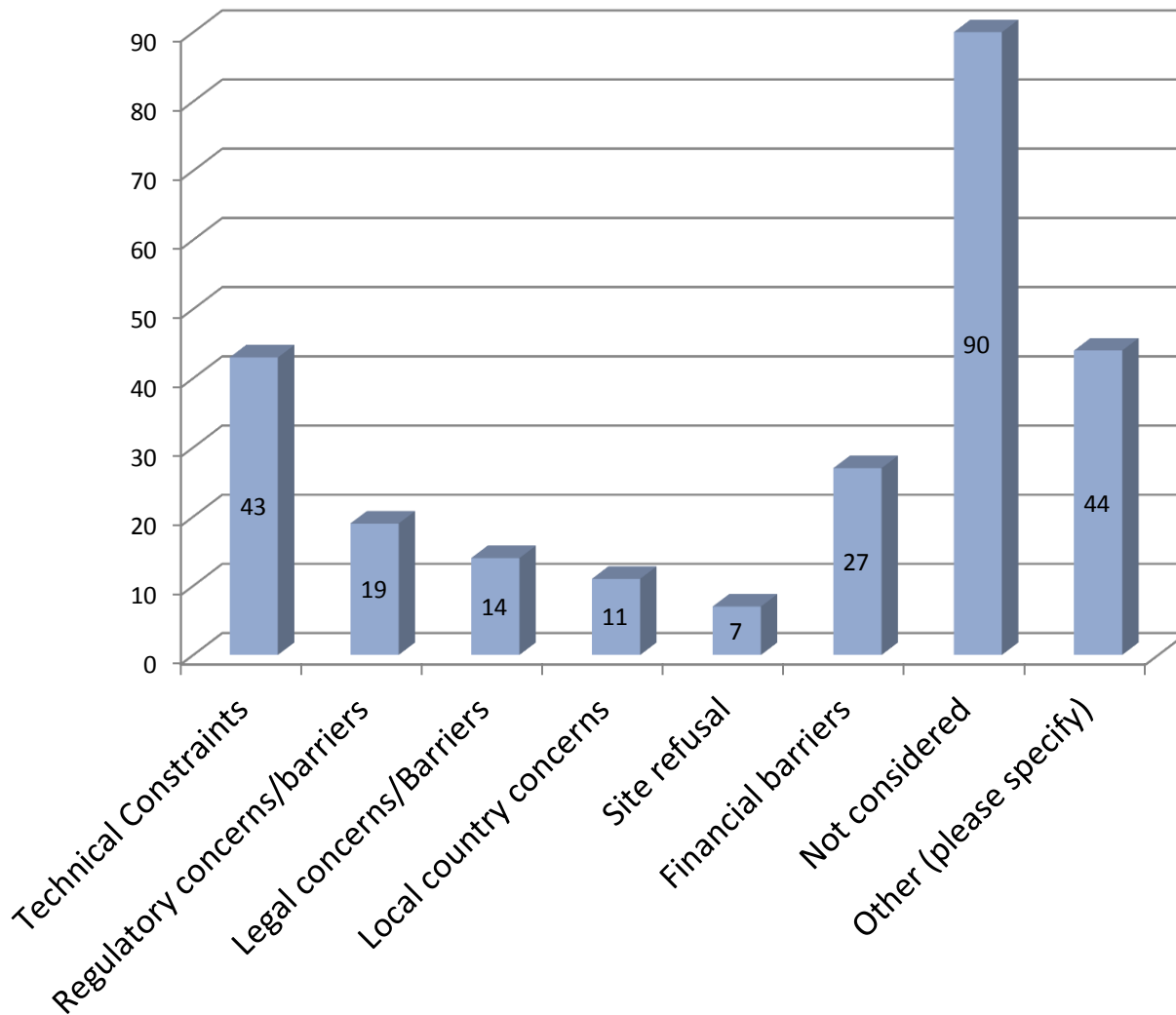
What % of trials have an eISF



Slight decrease in eISF growth from 2012 survey



Barriers to eISF uptake

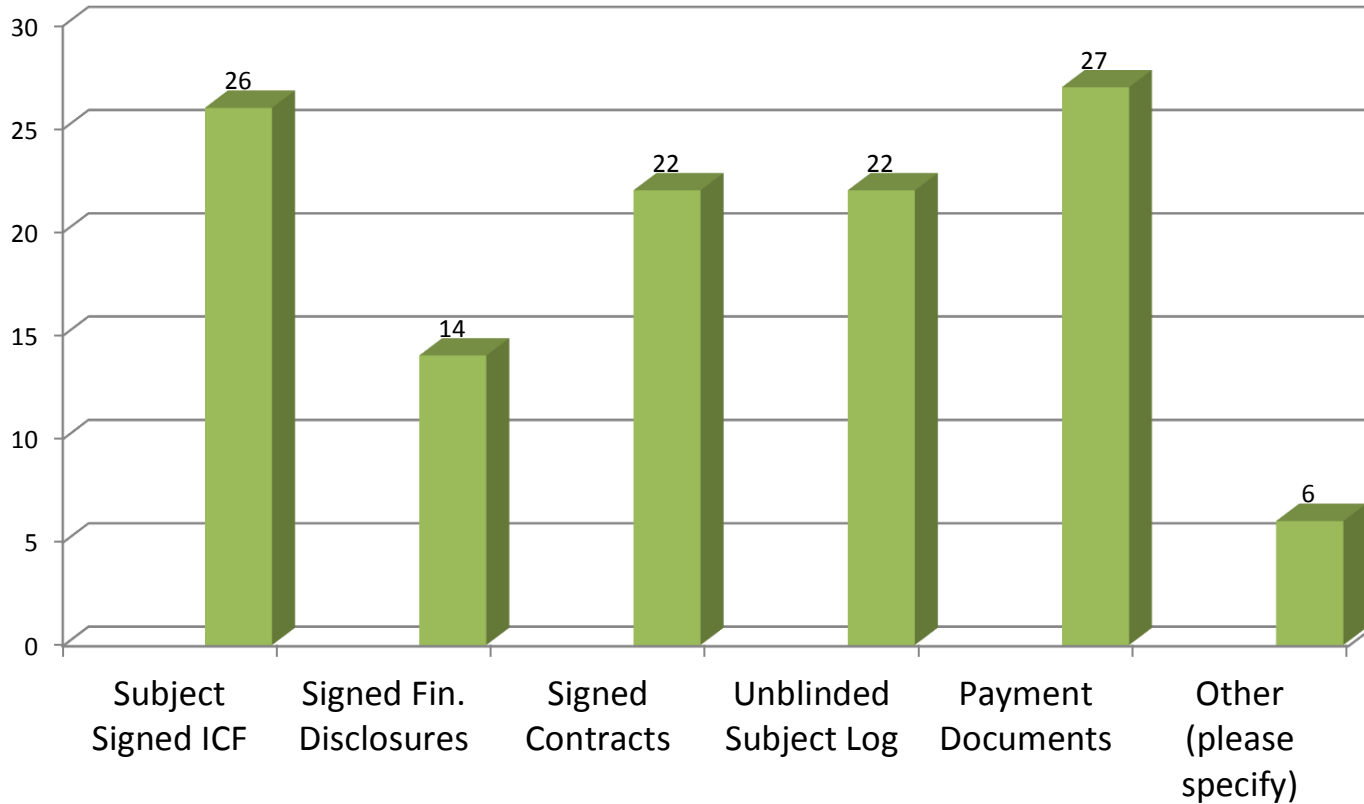


"Other" response themes

- Planning / building
- Still considering
- eTMF first
- Not there yet

Data and responses very similar to 2012 survey #2

Content not stored in eISF



"Other"

Source docs

Trends in Health Authority Inspections

Agency	eTMF inspections	Refused paper, requested eTMF	Refused eTMF, requested paper
US – FDA	17	1	1
EU – EMA	10	1	0
UK – MHRA	13	6	0
Japan – PMDA	3	0	0
Canada - Health Canada	2	0	0
Australia/New Z – ANZTPA	1	0	0
Brazil – ANVISA	1	0	0
China – SFDA	1	0	0
South Korea – KFDA	1	0	0
Switzerland - SwissMedic	1	1	0

Of additional interest, 7 non-premise, remote inspections identified

Remote (non-premise) inspection by any regulatory agency / health authority? Y (7), N (18), unk (3)

TMF Reference Model – Participate!

Contact co-chairs to join TMF Ref Model Team:

- Karen Redding, kredding@phlexglobal.com
- Lisa Mulcahy, mulcahy67@comcast.net

To stay up to date on TMF Ref Model team progress and active discussions, read the blog: <http://tmfrefmodel.blogspot.com/>

join **LinkedIn**  group “TMF Reference Model”
http://www.linkedin.com/groups?home=&gid=2663204&trk=anet_ug_hm

The TMF Ref Model and overview information is free and available here <http://www.diahome.org/en/News-and-Publications/Publications-and-Research/EDM-Corner.aspx>

TMF 2013 Survey sub-team – THANK YOU!

- Jennifer Gaskin
- Shah Ashraf
- Suellen Bigaj
- Christopher McSpiritt
- Karen Redding
- Fran Ross