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EUROPE INTERCHANGE

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**Buried Treasure: Bringing the Hidden Value of TMF
Metrics to Light**

Joanne Malia
Regeneron Pharmaceuticals
Janice Cassamajor
Cencora Pharmalex

Meet the Speakers

Joanne Malia

Title: Senior Director, Development Records Management

Organization: Regeneron Pharmaceuticals

Joanne Malia has served on the Steering Committee for the past 3 years and was the co-lead of the Change Control Board prior to that. She really enjoys the TMF and records in general and making the whole process easier and better quality while using metrics and working collaboratively with CROs and vendors. She is currently leading the TMF RM Risk Initiative and has been involved with inspections from FDA, MHRA, EMA, PMDA and others.



Janice Cassamajor

Title: Director Customer Success

Organization: Cencora Pharmalex

Janice Cassamajor, brings 15 years of experience in the TMF (Trial Master File) realm. As a customer success leader, her focus lies in fostering enduring partnerships. She is deeply devoted to upholding TMF integrity and is driven by a desire to assist others in attaining excellence in TMF management.





Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the authors and do not necessarily reflect the official policy or position of CDISC.*
- *The authors have no real or apparent conflicts of interest to report.*



Agenda

1. Value of the partnership
2. Use of data visualizations
3. Benefit to Quality



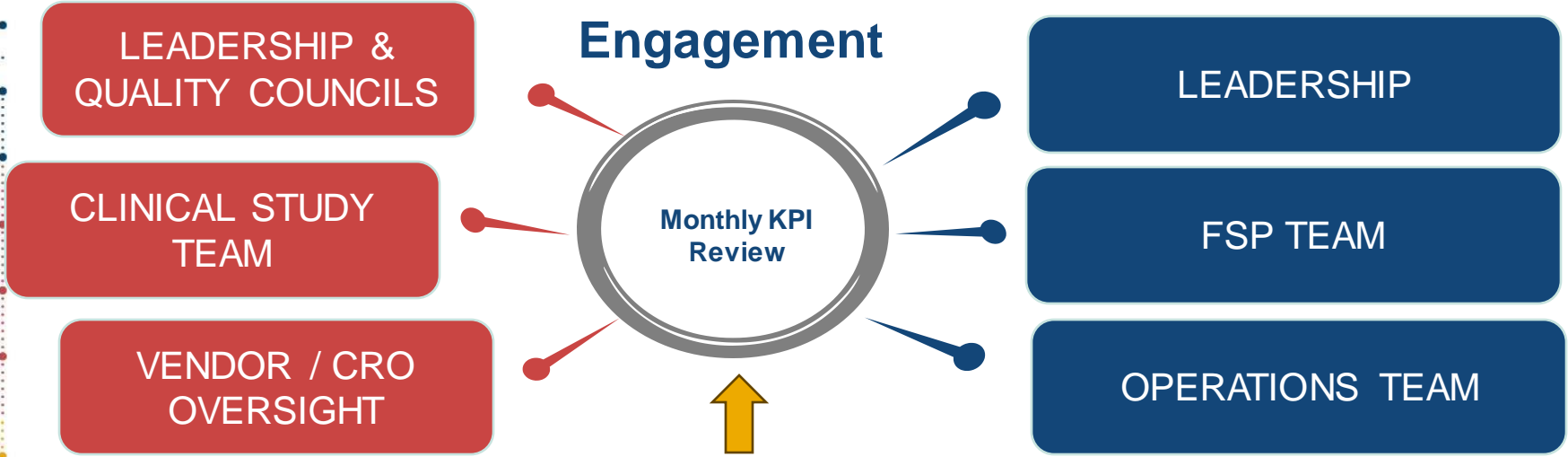
Collaborative Relationship

- Improved TMF quality, completeness and timeliness to help ensure ongoing inspection-readiness
- Developed and implemented process innovation that increases efficiency and frees busy study teams from rote work
- Created a “virtuous circle” of continuous improvements in TMF management and overall quality

How did we achieve this?

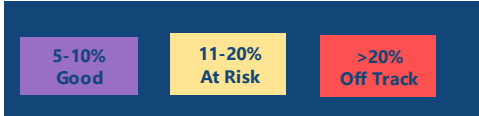
- Complete openness and transparency
- Collaboration with deep understanding
- Clear roles and responsibilities

Stakeholder Engagement



- eTMF reports
- Team trackers
- Historical data
- Deep dives
- Individual testimonials

Example - Quality Issues by CRO



CRO	Example Quality Issues by CRO Representing % of Total Docs Approved per CRO																																			
	Jan Qls	% of Total Docs submitted	Total docs submitted	Feb Qls	% of Total Docs submitted	Total docs submitted	Mar Qls	% of Total Docs submitted	Total docs submitted	Apr Qls	% of Total Docs submitted	Total docs submitted	May Qls	% of Total Docs submitted	Total docs submitted	Jun Qls	% of Total Docs submitted	Total docs submitted	Jul Qls	% of Total Docs submitted	Total docs submitted	Aug Qls	% of Total Docs submitted	Total docs submitted	Sep Qls	% of Total Docs submitted	Total docs submitted	Oct Qls	% of Total Docs submitted	Total docs submitted	Nov Qls	% of Total Docs submitted	Total docs submitted	Dec Qls	% of Total Docs submitted	Total docs submitted
A	437	6.30%	6987	555	6.10%	9144	774	6.60%	11672	764	6.60%	11504	750	5.60%	13511	616	4.80%	12717	519	4.50%	11532	471	4.60%	10343	598	5.60%	10603	832	6.20%	13477	927	6.6%	13993	865	6.1%	14191
B	66	18.10%	364	138	23.10%	598	203	21.60%	943	184	24.10%	762	196	21.90%	894	251	22.80%	1101	145	17.50%	827	284	20.30%	1402	198	11.40%	1742	202	25.20%	801	174	19.0%	915	160	17.1%	938
C	646	18.40%	1575	793	17.20%	4606	865	20.10%	4314	753	18.70%	4092	740	18.20%	4061	656	14.50%	4531	553	14.00%	3961	512	12.40%	4137	708	15.80%	4493	600	17.40%	3452	632	19.0%	3321	679	24.4%	2778
D	318	20.20%	1575	461	20.10%	2290	480	22.80%	2103	236	20.60%	1146	480	28.90%	1659	298	18.40%	1619	327	15.30%	2141	232	14.30%	1620	251	19.20%	1304	341	22.50%	1515	333	31.7%	1049	279	28.5%	979
E	466	23.90%	1946	686	24.70%	2778	673	27.40%	2328	540	24.10%	2241	632	22.30%	2839	617	17.80%	3459	410	12.10%	3378	548	20.20%	2717	516	18.30%	2812	558	20.10%	2783	645	25.0%	2576	571	23.5%	2434
F	504	25.00%	2020	572	29.90%	1913	646	34.90%	1820	513	31.10%	1648	765	27.20%	2816	488	23.50%	2077	481	22.00%	2191	495	25.60%	1936	398	20.30%	1958	362	19.70%	1839	446	23.5%	1899	342	23.4%	1461

Source: Regeneron; Cencora PharmaLex

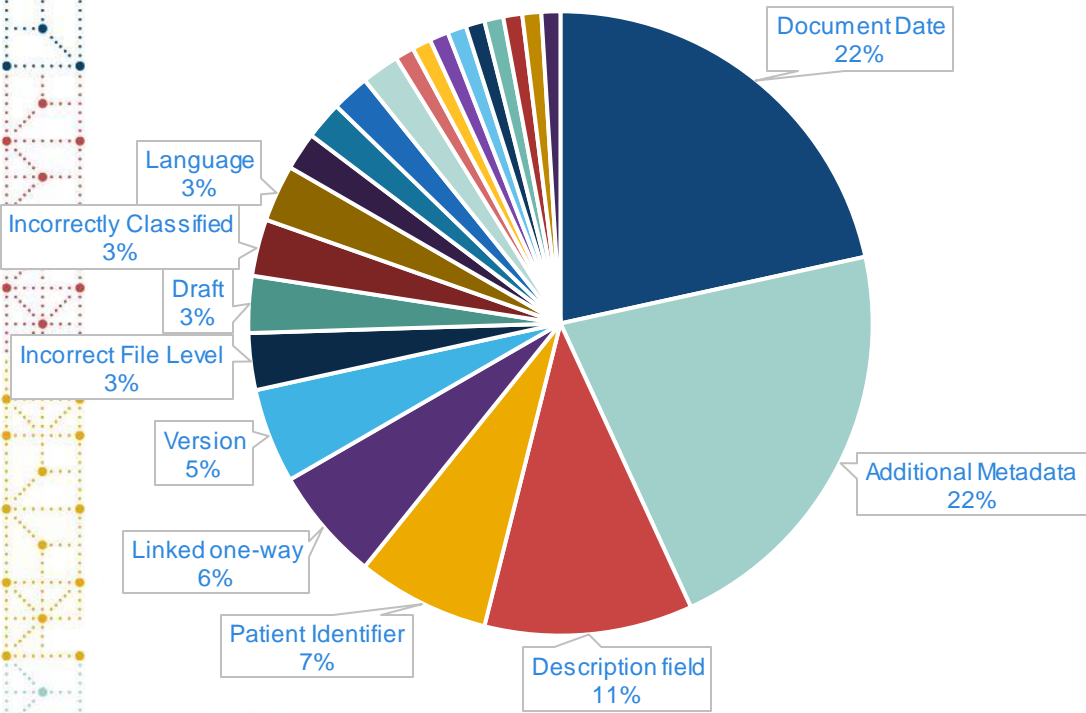


Example -Top 5 Artifacts with highest Pre-Approval QIs

All Studies

Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Classification QIs	Classification QIs	Classification QIs	Classification QIs	Classification QIs	Classification QIs	Classification QIs	Classification QIs	Classification QIs	Classification QIs	Classification QIs	Classification QIs
IRB or IEC Decision 240	IRB or IEC Decision/ 311	IRB or IEC Decision 270	ICH-GCP Training Certificate 187	Informed Consent Form (ICF) 240	IRB or IEC Decision 173	Informed Consent Form (ICF) 170	Meeting Material (Trial) 224	IRB or IEC Decision 154	ICH-GCP Training Certificate 164	Site Evidence of Training 230	Meeting Material (Trial) 215
Informed Consent Form (ICF) 151	ICH-GCP Training Certificate 286	ICH-GCP Training Certificate 259	Site Evidence of Training 176	IRB or IEC Decision 238	IP Shipment Documentation (IRT Only) 165	Meeting Material (Trial) 142	Informed Consent Form (ICF) 165	Meeting Material (Trial) 148	Meeting Material (Trial) 162	ICH-GCP Training Certificate 217	ICH-GCP Training Certificate 157
ICH-GCP Training Certificate 147	IRB or IEC Submission 283	Informed Consent Form (ICF) 228	Informed Consent Form (ICF) 163	ICH-GCP Training Certificate 181	Relevant Communications (Site) 148	Site Evidence of Training 124	ICH-GCP Training Certificate 132	ICH-GCP Training Certificate 147	Site Evidence of Training 147	Informed Consent Form (ICF) 182	IRB or IEC Decision 143
IRB or IEC Submission 137	Informed Consent Form (ICF) 253	Site Evidence of Training 187	IP Shipment Documentation (IRT Only) 141	Relevant Communications (Site) 178	Financial Disclosure Form (FDF) 155	IRB or IEC Decision 118	IRB or IEC Decision 118	Informed Consent Form (ICF) 124	IRB or IEC Decision 136	Meeting Material (Trial) 180	IRB or IEC Submission 135
Site Evidence of Training 127	Site Evidence of Training 197	IRB or IEC Submission 159	Relevant Communications (Site) 139	IRB or IEC Submission 152	Meeting Material (Trial) 139	ICH-GCP Training Certificate 117	IRB or IEC Submission 107	IRB or IEC Submission 118	Informed Consent Form (ICF) 100	IRB or IEC Decision 162	Relevant Communications (Site) 129

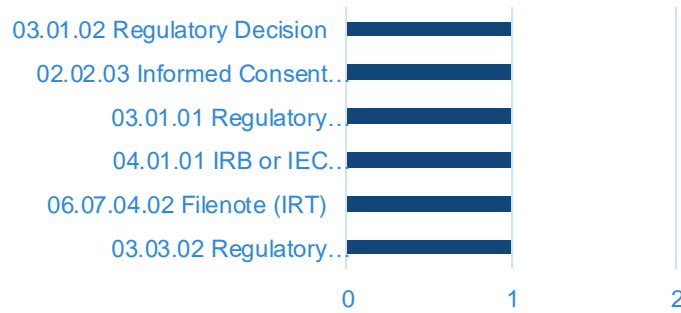
Example - QC findings by subcategory (top 5 by classification)



Description field



Linked one-way





Thank You!

