

Development of a Digital Audit Tracking Tool for FDA Audit Readiness

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1. Background

To facilitate ongoing readiness of cancer clinical trials (CCTs) at risk for inspection by the Food and Drug Administration (FDA), the Abramson Cancer Center (ACC) Lymphoma Group enrolled FDA inspection high-risk CCTs (FDA CCTs) in an external inspection support program (EIS) operated by the ACC Department of Operations, Compliance and Monitoring. At initial EIS enrollment of the first FDA CCT, there was no consistent audit preparation process in place for the Lymphoma Group. A digital audit tracking tool (ATT) was developed to create a uniform, streamlined, collaborative process that could be utilized for current and future CCTs.

2. Goals

- To create a streamlined, collaborative process for research team members to maintain FDA CCT participant binders in an audit-ready state
- To create a standardized audit tool template to be utilized for trials enrolled in the EIS program, as well as adapted for all current and future FDA CCTs
- To efficiently identify and resolve all missing and/or incomplete source documentation by aggregating trial data in an accessible and secure location

3. Solutions and Methods

The EIS program requirements necessitated creation of the ATT to enable all research team members to review participant binders in a standardized and collaborative fashion via an online Excel spreadsheet shared through Penn+ Box. Each research team member is given access to the ATT, which permits documentation, review of, and resolution of all missing/incomplete source documentation in participant binders. The ATT assures that all audit review progress is available for review by all members of the research team and enables preparation and maintenance of FDA CCT participant binders in an FDA inspection readiness state.

4. Outcomes

The ATT was first created for use for a specific FDA CCT. To this date, this trial has not undergone FDA inspection at the ACC. However, the utility and efficiency of the ATT has resulted in exemplary monitoring reviews by the EIS program. The processes for audit readiness have become more streamlined and collaborative across the Lymphoma Group and have resulted in similar exemplary monitoring reports in other EIS program-enrolled trials. For this reason, the ATT has been adapted and now utilized across many lymphoma studies that have enrolled in the EIS audit readiness program.

5. Lessons Learned and Future Directions

The use of the ATT has been essential and extremely successful in maintaining audit-ready trial documentation across many studies in the Lymphoma Group enrolled in the EIS program. Initial implementation of the ATT was targeted for one FDA CCT. Its efficiency and inherent collaborative nature have resulted in the ATT being adapted for use in other FDA CCTs, based upon feedback from Lymphoma Group research staff. Suggestions have included: 1) the need for less data to be housed on one page of the ATT, and 2) the utilization of “tracked changes” for decreased margin of error in

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corrective data entry. The ATT will continue to be shared with other Clinical Research Unit research groups for implementation by their research staff for trials enrolled in the EIS program.

Figure

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 Confirmed missing ->
 Source Document ->
 Source Document not applicable to subject

	A	B	C	D	E	F	T	U	V	Y	Z	AE	AF	AG	AH	AI	
		Active Treatment	Long Term Follow-up				Post Tx Follow-up				Off Study						
2	Subject ID	105652	105623	105638	105410	105643	103644	103682	103658	105221	105428	104577	104816	104837	104884	105335	N/A
3	Screening Number	2797	2901	2924	2786	2416	2235	2366	2254	2734	2809/2819	2469	2510	2527	2660	2804	
4	Imaging																
5	Baseline RECIST W/Report	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N/A
6	Optional 6 Wk RECIST W/ Report	Y	Y	Y	N/A	N/A	N/A	N/A	Y	N/A	Y	N/A	Y	N/A	Y	N/A	N/A
7	F/U 1 RECIST W/Report	Y	Y	Y	Y	Y	Y	Y	Y	Y	N/A	N/A	N/A	N/A	Y	N/A	N/A
8	F/U 2 RECIST W/Report	N/A	N/A	N/A	Y	Y	Y	Y	N/A	Y	N/A	N/A	N/A	N/A	N/A	N/A	N/A
9	F/U 3 RECIST W/Report	N/A	N/A	N/A	N/A	Y	Y	Y	N/A	Y	N/A	N/A	N/A	N/A	N/A	N/A	N/A
10	F/U 4 RECIST W/Report	N/A	N/A	N/A	N/A	N/A	N/A	Y	N/A	Y	N/A	N/A	N/A	N/A	N/A	N/A	N/A
11	Screening	8/16/2021	10/16/2021	1/23/2022	2/28/2022	4/14/2022	3/7/2021	5/23/2021	7/18/2021	8/5/2021	4/12/2021	3/12/2021	3/14/2021	4/6/2021	8/2/2021	9/15/2021	
12	Slot Req Form	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
13	Eligibility Packet	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
14	ICF	Y	N/A	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
15	Labs	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
16	Covance Req	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
17	Covance Registration	Y	N/A	Y	Y	Y					Y	Y	Y	Y			
18	BMBx local	Y	Y	Y	Y	Y	Y	Y	Y		Y	Y	N/A	N/A	Y	N/A	N/A
19	BMBx central	Y	Y	Y	Y	Y				Y	Y	Y	N/A	N/A		N/A	
20	Path Report	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
21	Scan Reports	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
22	TTAB/BioBank	Y	Y	Y	Y	N/A	Y	Y	Y	Y	Y	Y	Y	Y	Y	N/A	N/A
23	Tumor Biopsy	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N/A	Y	Y	Y	N/A
24	RECIST	Y	Y	Y	Y	Y			N/A	Y	Y	Y	Y	Y	Y	Y	N/A
25	MD Note	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
26	RN Note	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
27	MMSE	N/A	N/A	N/A	N/A	N/A	Y	Y	Y	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
28	ECG	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
29	Phone Encounters	Y	N/A	Y	N/A	N/A	Y	N/A	N/A	N/A	Y	N/A	Y	N/A	Y	Y	Y
30	Sponsor Correspondence	Y	Y	Y	Y	Y	Y	Y	N/A	Y	Y	Y	N/A	Y	Y	Y	Y
31	Sponsor enrollment confirm.	Y	Y	Y	Y	Y				Y	Y		N/A				
32	Internal Emails	N/A	N/A	N/A	N/A	N/A	Y	Y	N/A	N/A	N/A	N/A	Y	Y	N/A	N/A	N/A
33	CID1	10/16/2021	12/7/2021	2/28/2022	4/5/2022	5/18/2022	4/3/2021	6/20/2021	8/15/2021	9/2/2021	5/7/2021	4/9/2021	N/A	N/A	8/30/2021	10/10/2021	N/A
34	Labs	Y	Y	Y	Y	Y	Y	Y	N/A	Y	Y	Y	N/A	N/A	Y	Y	N/A
35	Covance Req	Y	Y		Y	Y	Y	Y	N/A	Y	Y	Y	N/A	N/A	Y	Y	N/A
36	MD Note	Y	Y	Y	Y	Y	Y	Y	N/A	Y	Y	Y	N/A	N/A	Y	Y	N/A
37	RN Note	Y	Y	Y	Y	Y	Y	Y	N/A	Y	Y	Y	N/A	N/A	Y	Y	N/A
38	CHPS Note	N/A	Y	N/A	Y	Y	Y	Y	N/A	Y	Y	Y	N/A	N/A	Y	Y	N/A