Development of a Digital Audit Tracking Tool for FDA Audit Readiness

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BACKGROUND

To facilitate on-going 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 (DOCM). At initial EIS enrollment of the first high risk 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, stream-lined, collaborative process which could be utilized for current and future CCTs.

GOALS

- To create a stream-lined, online, 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

First Iteration of Audit Tracking Tool for FDA Inspection Readiness

Present in Chart
Unconfirmed Missing in Chart
Confirmed Missing in Chart
Not Applicable to Subject

	A	B	C	D	E	F	T	U	V	Y
1		Active Treatment		Long Term Follow-up			Post Tx Follow-up			
2	Subject ID	105652	105623	105638	105410	105643	103644	103682	103658	
3	Screening Number	2797	2901	2924	2786	2416	2235	2366	2254	
4	Imaging									
5	Baseline RECIST W/Report	Y	Y	Y	Y	Y	Y	Y	Y	Y
6	Optional 6 Wk RECIST W/ Report	Y	Y	Y	N/A	N/A	N/A	N/A	Y	N/A
7	F/U 1 RECIST W/Report	Y	Y	Y	Y	Y	Y	Y	Y	Y
8	F/U 2 RECIST W/Report	N/A	N/A	N/A	Y	Y	Y	Y	N/A	Y
9	F/U 3 Recist W/Report	N/A	N/A	N/A	N/A	Y	Y	Y	N/A	
10	F/U 4 RECIST W/Report	N/A	N/A	N/A	N/A	N/A	N/A	Y	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	
12	Slot Req Form	Y	Y	Y	Y	Y	Y	Y	Y	Y
13	Eligibility Packet	Y	Y	Y	Y	Y	Y	Y	Y	Y
14	ICF	Y	N/A	Y	Y	Y	Y	Y	Y	Y
15	Labs	Y	Y	Y	Y	Y	Y	Y	Y	Y
16	Covance Req	Y	Y	Y	Y	Y	Y	Y	Y	
17	Covance Registration	Y	N/A	Y	Y	Y				
18	BMBx local	Y	Y	Y	Y	Y	Y	Y	Y	
19	BMBx central	Y	Y	Y	Y	Y				Y

Online & Protected

Efficient & Timely Audits

Uniform & Collaborative

Second Iteration of Audit Tracking Tool for FDA Inspection Readiness Following EIS

Complete Subject Data

Separation of Subject Data

Reduction of Human Error

	A	B	C	D	E
1					
2	Subject ID	105652			
3	Screening Number	2797			
4	Diagnoses	Follicular Lymphoma			
5	Study Status	Active On Study			
6	ICFs	IRB Approval Date		Subject Signature Date	Comments
7	V 2.0	6/20/2021		8/16/2021	
8	V 3.0	9/18/2021		10/12/2021	
13	CT/MRI	Window		Y/N	Comments
14	CT/MRI Week 1			Y	CT W/ Contrast
15	CT/MRI Week 8			N/A	
16	CT/MRI Week 16			N/A	
22					
23	Time Points	Window		Y/N	Comments
24	Screening	D-21 to D1		(08/16/2021)	
25	Slot Req Form	8/16/2021	9/6/2021	Y	Found in eligibility packet
26	Eligibility Packet	8/16/2021	9/6/2021	Y	
27	Labs	8/16/2021	9/6/2021	Y	
61	Phone Encounters	8/16/2021	9/6/2021	Y	3 phone encounters
62	Sponsor Correspondence	8/16/2021	9/6/2021	Y	
63	Sponsor enrollment confirm.	8/16/2021	9/6/2021	Y	
64	Internal Emails	8/16/2021	9/6/2021	Y	12 internal emails
65	C1D1	+1d		(09/06/2021)	
96	C1D8	+1d		(09/14/2021)	
97	Labs	9/14/2021	9/15/2021	Y	

Subject 1 (EXP) | Subject 2 (EXP) | Subject 3 (EXP) | Subject 4 (EXP) ...

SOLUTIONS/ 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. 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 a FDA-inspection readiness state.

OUTCOMES

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.

LESSONS LEARNED / FUTURE DIRECTIONS

The use of the ATT has been essential and its collaborative nature has resulted in the ATT being adapted for use in other FDA CCTs. The ATT will continue to be shared with other CRU research groups for implementation by their research staff for their CCTs enrolled in the EIS program.

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