

Screen Failure Tracking Log – Trial-Level

Audience: Clinical trial staff manager

Principal Investigator:

Protocol #:

Study Title:

Sponsor:

Provided by clinical site staff
conducting screening

KEY CONSIDERATIONS

1. Is the screen failure tied directly to a protocol-specified exclusion criteria?
2. Is the screen failure determined based on an objective measure of eligibility (lab value, etc.)?
3. Is the screen failure determined based on a subjective assessment or judgement (i.e., investigator discretion)?

Participant*	Date Screened	Reason for Exclusion/Screen Failure	Screen Failure Assessment**		Initials of Assessor
			Protocol-specified exclusion criteria AND/OR objective measure	Study staff or investigator discretion / judgement	
1			<input type="checkbox"/>	<input type="checkbox"/>	
2			<input type="checkbox"/>	<input type="checkbox"/>	
3			<input type="checkbox"/>	<input type="checkbox"/>	
4			<input type="checkbox"/>	<input type="checkbox"/>	
5			<input type="checkbox"/>	<input type="checkbox"/>	
6			<input type="checkbox"/>	<input type="checkbox"/>	
7			<input type="checkbox"/>	<input type="checkbox"/>	
8			<input type="checkbox"/>	<input type="checkbox"/>	
9			<input type="checkbox"/>	<input type="checkbox"/>	
10			<input type="checkbox"/>	<input type="checkbox"/>	

*Use a pre-screening number, initials, or first name to identify individuals at pre-screening, to be HIPAA compliant.

**Assessment made by clinical trial staff manager and/or investigator. Tracking these assessment data can enable an understanding of whether a particular site has justified screen failures over time. Stratifying these assessment data by participant demographics (collected on the Eligibility & Enrollment Log) can enable understanding of the demographics of screen failure, and whether objective assessments are utilized for participants of particular demographic groups.