

LOST Information in Trials (LOST-IT) study

Data abstraction Form

Screener initials: _____	Study ID: _____	Author, year: _____, _____
Journal: <input type="checkbox"/> AIM <input type="checkbox"/> BMJ <input type="checkbox"/> JAMA <input type="checkbox"/> Lancet <input type="checkbox"/> NEJM		

1. Eligible RCT? No **Exclude, stop here**
 Yes, type of RCT:
 Two arms Multiple Arms
 Factorial design Report of longer follow up time
 Report of secondary analysis Report of subgroup analysis
2. Trial described as: Non-inferiority
 Equivalence
 Neither
3. Primary outcome clearly specified Yes, one: _____ (go to q5)
 No, multiple primary outcomes: _____
_____ (go to q4)
 None specified (go to q4)
4. If multiple or no primary outcome specified, select one : _____
5. Primary outcome category # (refer to the guide): _____ (e.g. II.3)
6. Effect on primary endpoint reported as: Continuous outcome exclusively **Exclude**
 Multinomial outcome exclusively **Exclude**
 Binary outcome expressed as rate exclusively **Exclude**
 Binary outcome, data not available for 2x2 table **Exclude**
 Binary outcome, data available for 2x2 table, go to the next question
7. Is it a composite endpoint? Yes, list components: _____
 No
8. Is it a patient important outcome? No **Exclude**
 Yes, go to the next question
9. Result statistically significant? No **Exclude**
 Yes

Please fill out this box for each study

<input type="checkbox"/> Include in LOST-IT
<input type="checkbox"/> Exclude from LOST-IT
<input type="checkbox"/> 3rd reviewer needed (no consensus between 2 reviewers)

If exclude, reason for exclusion:
<input type="checkbox"/> Not RCT
<input type="checkbox"/> Not eligible RCT
<input type="checkbox"/> Data for the primary endpoint not available for 2x2 table
<input type="checkbox"/> Outcome not patient important
<input type="checkbox"/> Result not statistically significant

BACKGROUND INFORMATION																																
10.	Number of study centers	n =																														
11.	Funding <i>Check all that Apply</i>	<input type="checkbox"/> Private for profit, industry only supplying medication <input type="checkbox"/> Private for profit, other <input type="checkbox"/> Private not for profit <input type="checkbox"/> Governmental <input type="checkbox"/> Not funded <input type="checkbox"/> Not reported																														
12.	Clinical area <i>Check only one</i>	<table border="0"> <tr> <td>Medical</td> <td>Surgical</td> </tr> <tr> <td><input type="checkbox"/> Dermatology</td> <td><input type="checkbox"/> Cardiac surgery</td> </tr> <tr> <td><input type="checkbox"/> Cardiology</td> <td><input type="checkbox"/> General surgery</td> </tr> <tr> <td><input type="checkbox"/> Endocrinology</td> <td><input type="checkbox"/> Obstetrics/ Gynecology</td> </tr> <tr> <td><input type="checkbox"/> Gastro Intestinal</td> <td><input type="checkbox"/> Ophthalmology</td> </tr> <tr> <td><input type="checkbox"/> Hematology</td> <td><input type="checkbox"/> Orthopedic surgery</td> </tr> <tr> <td><input type="checkbox"/> Intensive Care</td> <td><input type="checkbox"/> Otorhinolaryngology (ENT: Ear Nose Throat)</td> </tr> <tr> <td><input type="checkbox"/> Infectious Diseases</td> <td><input type="checkbox"/> Neurosurgery</td> </tr> <tr> <td><input type="checkbox"/> Neurology</td> <td><input type="checkbox"/> Plastic surgery</td> </tr> <tr> <td><input type="checkbox"/> Oncology</td> <td><input type="checkbox"/> Thoracic surgery</td> </tr> <tr> <td><input type="checkbox"/> Psychiatric</td> <td><input type="checkbox"/> Urologic surgery</td> </tr> <tr> <td><input type="checkbox"/> Renal</td> <td><input type="checkbox"/> Vascular surgery</td> </tr> <tr> <td><input type="checkbox"/> Respiratory</td> <td><input type="checkbox"/> Other (<i>specify</i>):</td> </tr> <tr> <td><input type="checkbox"/> Rheumatology</td> <td></td> </tr> <tr> <td><input type="checkbox"/> Other (<i>specify</i>):</td> <td></td> </tr> </table>	Medical	Surgical	<input type="checkbox"/> Dermatology	<input type="checkbox"/> Cardiac surgery	<input type="checkbox"/> Cardiology	<input type="checkbox"/> General surgery	<input type="checkbox"/> Endocrinology	<input type="checkbox"/> Obstetrics/ Gynecology	<input type="checkbox"/> Gastro Intestinal	<input type="checkbox"/> Ophthalmology	<input type="checkbox"/> Hematology	<input type="checkbox"/> Orthopedic surgery	<input type="checkbox"/> Intensive Care	<input type="checkbox"/> Otorhinolaryngology (ENT: Ear Nose Throat)	<input type="checkbox"/> Infectious Diseases	<input type="checkbox"/> Neurosurgery	<input type="checkbox"/> Neurology	<input type="checkbox"/> Plastic surgery	<input type="checkbox"/> Oncology	<input type="checkbox"/> Thoracic surgery	<input type="checkbox"/> Psychiatric	<input type="checkbox"/> Urologic surgery	<input type="checkbox"/> Renal	<input type="checkbox"/> Vascular surgery	<input type="checkbox"/> Respiratory	<input type="checkbox"/> Other (<i>specify</i>):	<input type="checkbox"/> Rheumatology		<input type="checkbox"/> Other (<i>specify</i>):	
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METHODOLOGICAL QUALITY				
15.	Concealment of Allocation <i>Check only one</i>	<input type="checkbox"/> Sequentially numbered, opaque, sealed envelope	<input type="checkbox"/> Coded medication containers	<input type="checkbox"/> Central randomization
		<input type="checkbox"/> Envelopes, other	<input type="checkbox"/> Open random allocation schedule	<input type="checkbox"/> Quasi-randomized
		<input type="checkbox"/> "Concealed", no method described	<input type="checkbox"/> "Not concealed"	<input type="checkbox"/> Not reported
16.	Blinding of patients	<input type="checkbox"/> Definitely yes	<input type="checkbox"/> Probably yes	<input type="checkbox"/> Probably not
				<input type="checkbox"/> Definitely not
17.	Blinding of health Care providers	<input type="checkbox"/> Definitely yes	<input type="checkbox"/> Probably yes	<input type="checkbox"/> Probably not
				<input type="checkbox"/> Definitely not
18.	Blinding of data collectors	<input type="checkbox"/> Definitely yes	<input type="checkbox"/> Probably yes	<input type="checkbox"/> Probably not
				<input type="checkbox"/> Definitely not
19.	Blinding of outcome adjudicators	<input type="checkbox"/> Definitely yes	<input type="checkbox"/> Probably yes	<input type="checkbox"/> Probably not
				<input type="checkbox"/> Definitely not
20.	Blinding of data analysts	<input type="checkbox"/> Definitely yes	<input type="checkbox"/> Probably yes	<input type="checkbox"/> Probably not
				<input type="checkbox"/> Definitely not
21.	Study stopped early for benefit	<input type="checkbox"/> Yes	<input type="checkbox"/> No	

ITT PRINCIPLE				
22.	Authors used the term ITT	<input type="checkbox"/> Yes, "ITT"	<input type="checkbox"/> Yes, "modified ITT"	<input type="checkbox"/> No
23.	Post randomization exclusion of mistakenly randomized	<input type="checkbox"/> Definitely yes	<input type="checkbox"/> Probably yes	<input type="checkbox"/> Probably not
				<input type="checkbox"/> Definitely not
24.	Information about ineligibility was available at randomization	<input type="checkbox"/> Definitely yes	<input type="checkbox"/> Probably yes	<input type="checkbox"/> Probably not
				<input type="checkbox"/> Definitely not
25.	Post randomization exclusions were blinded to allocation	<input type="checkbox"/> Definitely yes	<input type="checkbox"/> Probably yes	<input type="checkbox"/> Probably not
				<input type="checkbox"/> Definitely not
26.	Patients for whom outcome data is available were analyzed in the arm to which they were randomized	<input type="checkbox"/> Definitely yes	<input type="checkbox"/> Probably yes	<input type="checkbox"/> Probably not
				<input type="checkbox"/> Definitely not

LTFU STATEMENTS				
27.	LTFU explicitly reported	<input type="checkbox"/> Explicit statement: LTFU occurred	<input type="checkbox"/> Explicit statement: LTFU did not occur	<input type="checkbox"/> No explicit statement about LTFU
28.	CONSORT flow diagram	<input type="checkbox"/> CONSORT diagram showing LTFU	<input type="checkbox"/> CONSORT diagram not showing LTFU	<input type="checkbox"/> No CONSORT diagram
29.	For studies with no explicit statement about LTFU and no consort diagram	<input type="checkbox"/> Meet all "3 criteria" (see instructions)	<input type="checkbox"/> Does not meet all "3 criteria" (see instructions)	<input type="checkbox"/> N/A
30.	LTFU reported separately for the 2 arms	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
31.	LTFU reported for each time point in which effect estimate for 1 ^{ary} outcome is reported in this article	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A (only one effect estimate reported)
32.	Authors compared baseline characteristics of LTFU	<input type="checkbox"/> Yes, LTFU group vs. non LTFU group	<input type="checkbox"/> Yes, LTFU 1 st arm vs. LTFU 2 nd arm	<input type="checkbox"/> No
33.	Implications of LTFU discussed	<input type="checkbox"/> Yes <input type="checkbox"/> No		
34.	Method of dealing with LTFU explicitly described (check all that apply)	<input type="checkbox"/> Yes, survival analysis	<input type="checkbox"/> Yes, in "methods"	<input type="checkbox"/> Yes, in "results" <input type="checkbox"/> No

35. METHOD OF DEALING WITH LTFU (for the primary outcome)			
Method	Primary analysis (check at least and only one)	Additional analyses (check all applicable)	
Not applicable, no LTFU occurred	<input type="checkbox"/>	<input type="checkbox"/>	
Not applicable, uncertain whether LTFU occurred	<input type="checkbox"/>	<input type="checkbox"/>	
Unclear which method used	<input type="checkbox"/>	<input type="checkbox"/>	
Survival analysis (censored at the time of LTFU)	<input type="checkbox"/>	<input type="checkbox"/>	
Complete case analysis	<input type="checkbox"/>	<input type="checkbox"/>	
Worst case scenario	<input type="checkbox"/>	<input type="checkbox"/>	
Best case scenario	<input type="checkbox"/>	<input type="checkbox"/>	
None of the LTFU had the outcome	<input type="checkbox"/>	<input type="checkbox"/>	
All LTFU had the outcome	<input type="checkbox"/>	<input type="checkbox"/>	
LTFU had same outcome incidence as their group	<input type="checkbox"/>	<input type="checkbox"/>	
LTFU had higher outcome incidence than their group, same incidence in 2 study groups	<input type="checkbox"/>	<input type="checkbox"/>	
LTFU had higher outcome incidence than their group, different incidence in 2 study groups	<input type="checkbox"/>	<input type="checkbox"/>	
Different methods for different subgroups of LTFU:	<input type="checkbox"/>	<input type="checkbox"/>	
Other (specify):	<input type="checkbox"/>	<input type="checkbox"/>	

LTFU STATISTICAL DATA					
36. Primary outcome selected for LOST-IT (q3 or q4): _____ <input type="checkbox"/> Check here if outcome was reversed from positive to negative					
37. Follow-up time point (value): _____					
38. Unit of time: <input type="checkbox"/> minutes <input type="checkbox"/> hours <input type="checkbox"/> days <input type="checkbox"/> weeks <input type="checkbox"/> months <input type="checkbox"/> years					
39. Type of measure: <input type="checkbox"/> fixed period <input type="checkbox"/> mean <input type="checkbox"/> median <input type="checkbox"/> minimum <input type="checkbox"/> maximum					
	<i>This table relates to the <u>primary analysis</u> of the <u>primary outcome</u></i>	Intervention	Control	Total	<input type="checkbox"/> Different assumptions for different subgroups of LTFU (circle one choice, see instructions)
40.	<input type="checkbox"/> Mistakenly randomized, inappropriately excluded (subtotal 1)				1 2 3 4 5
41.	<input type="checkbox"/> Did not receive intervention, inappropriately excluded (subtotal 2)				1 2 3 4 5
42.	<input type="checkbox"/> Withdrew consent (subtotal 3) <input type="checkbox"/> unclear whether followed up <input type="checkbox"/> not followed up <input type="checkbox"/> followed up, not included in the analysis (not LTFU for LOST-IT)				
43.	<i>Withdrew consent due to side effect or adverse events</i>				1 2 3 4 5
44.	<i>Withdrew consent due to other specified reason:</i>				1 2 3 4 5
45.	<i>Withdrew consent due to unclear reason</i>				1 2 3 4 5
46.	<input type="checkbox"/> Cross over (subtotal 4) <input type="checkbox"/> unclear whether followed up <input type="checkbox"/> not followed up <input type="checkbox"/> followed up, not included in the analysis (not LTFU for LOST-IT) <input type="checkbox"/> followed up, analyzed in a group not randomized to (not LTFU for LOST-IT)				
47.	<i>Cross over due to side effect or adverse events</i>				1 2 3 4 5
48.	<i>Cross over due to other specified reason:</i>				1 2 3 4 5
49.	<i>Cross over due to unclear reason</i>				1 2 3 4 5
50.	<input type="checkbox"/> Non adherent (subtotal 5) <input type="checkbox"/> unclear whether followed up <input type="checkbox"/> not followed up <input type="checkbox"/> followed up, not included in the analysis (not LTFU for LOST-IT) <input type="checkbox"/> followed up, analyzed in a group not randomized to (not LTFU for LOST-IT)				
51.	<i>Non adherent due to side effect or adverse events</i>				1 2 3 4 5
52.	<i>Non adherent due to other specified reason:</i>				1 2 3 4 5
53.	<i>Non adherent due to unclear reason</i>				1 2 3 4 5
54.	<input type="checkbox"/> Lost contact and no other source of outcome data (subtotal 6)				1 2 3 4 5

55.	<input type="checkbox"/> Other (or no reported) reason for LTFU: _____, (subtotal 7) <input type="checkbox"/> unclear whether followed up <input type="checkbox"/> not followed up <input type="checkbox"/> followed up, not included in the analysis (not LTFU for LOST-IT)				1 2 3 4 5
56.	<input type="checkbox"/> Different categories of LTFU reported together: _____, (subtotal 8) <input type="checkbox"/> unclear whether followed up <input type="checkbox"/> not followed up <input type="checkbox"/> followed up, not included in the analysis (not LTFU for LOST-IT)				1 2 3 4 5
57.	LTFU, total				

This table relates to the <u>primary analysis</u> of the <u>primary outcome</u>		Intervention		Control		Total			
		Total	Events	Total	Events	Total	Events		
58.	Mistakenly randomized, appropriately excluded								
59.	Did not receive intervention, appropriately excluded								
60.	Excluded as part of center exclusion								
61.	Randomized								
62.	Randomized\$ (Randomized – appropriately excluded 61-(58+59+60))								
63.	Included in primary analysis								
64.	Followed-up								
65.	Measure of effect estimate	<input type="checkbox"/> RR		<input type="checkbox"/> HR		<input type="checkbox"/> OR		<input type="checkbox"/> RRR	
		<input type="checkbox"/> ARR/ARI		<input type="checkbox"/> Time ratio		<input type="checkbox"/> Cumulative incidence ratio			
66.	Unadjusted Effect estimate; 95% CI; p value	_____ (_____; _____); p=_____							
67.	Adjusted Effect estimate; 95% CI; p value	_____ (_____; _____); p=_____							

68.	Inconsistency in LTFU data (explain below)
69.	Misunderstanding of LTFU or questionable inferences (explain below)
70.	Time required to complete this form: _____ min
71.	<input type="checkbox"/> Check here if we need to ask authors for numbers per study arm (if only total numbers reported) <input type="checkbox"/> Check here if we need to ask authors for the total number of LTFU (if not reported)