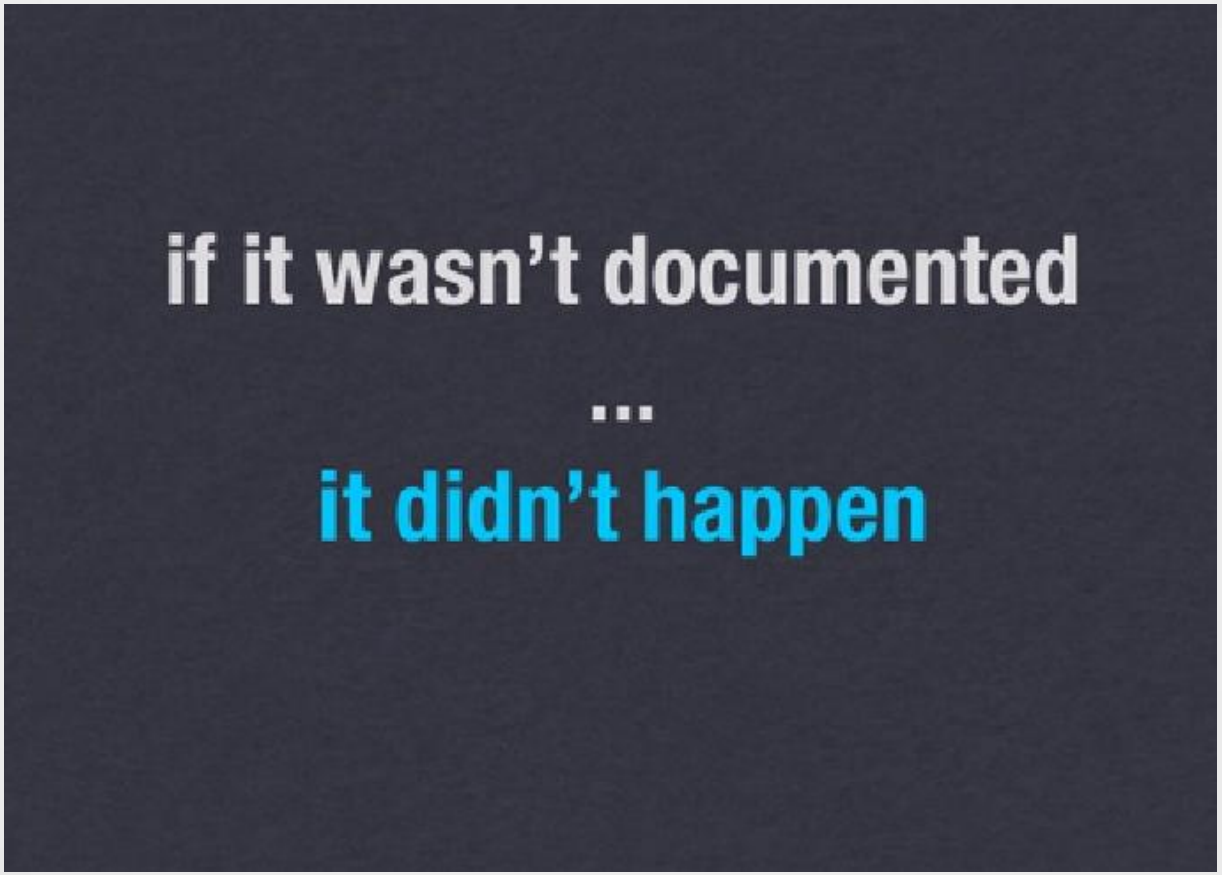
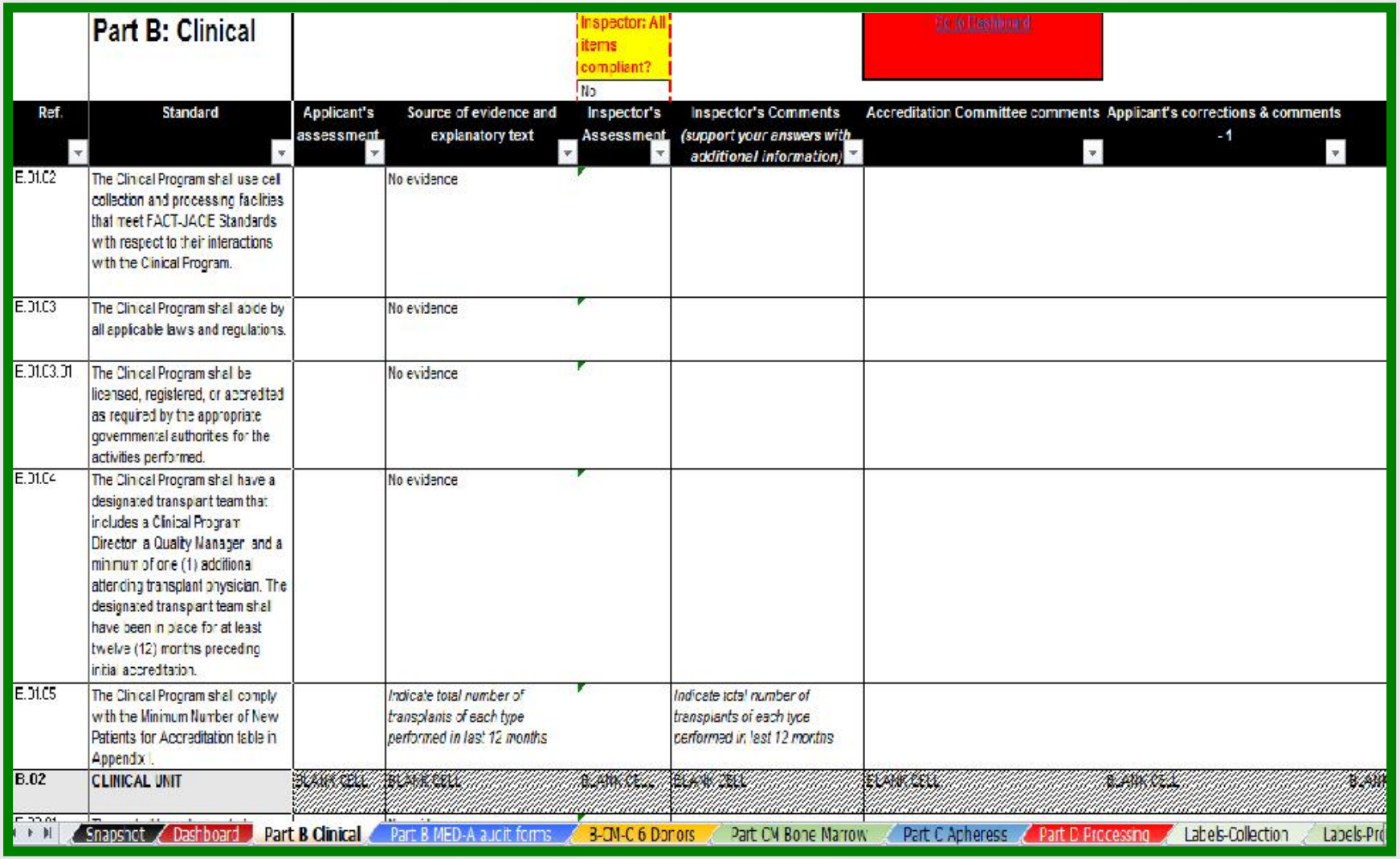
Inspection Reports


if it wasn't documented
...
it didn't happen

www.jacie.org/document-centre

CHECKLIST



	Part B: Clinical			Inspector: All items compliant? No		Go to Dashboard	
Ref.	Standard	Applicant's assessment	Source of evidence and explanatory text	Inspector's Assessment	Inspector's Comments *(support your answers with additional information)*	Accreditation Committee comments	Applicant's corrections & comments - 1
E.01.02	The Clinical Program shall use cell collection and processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Clinical Program.		No evidence				
E.01.03	The Clinical Program shall abide by all applicable laws and regulations.		No evidence				
E.01.03.01	The Clinical Program shall be licensed, registered, or accredited as required by the appropriate governmental authorities for the activities performed.		No evidence				
E.01.04	The Clinical Program shall have a designated transplant team that includes a Clinical Program Director, a Quality Manager, and a minimum of one (1) additional attending transplant physician. The designated transplant team shall have been in place for at least twelve (12) months preceding initial accreditation.		No evidence				
E.01.05	The Clinical Program shall comply with the Minimum Number of New Patients for Accreditation table in Appendix I.		*Indicate total number of transplants of each type performed in last 12 months*		*Indicate total number of transplants of each type performed in last 12 months*		
B.02	CLINICAL UNIT	BLANK CELL	BLANK CELL	BLANK CELL	BLANK CELL	BLANK CELL	BLANK CELL

Snapshot | Dashboard | Part B Clinical | Part B MED-A audit forms | B-CM-C 6 Donors | Part CM Bone Marrow | Part C Apheresis | Part D Processing | Labels-Collection | Labels-Pr

SUMMARY REPORT

Inspection Summary Report

Inspection Report and Recommendations to Applicant

Contents

What is the best way to work on a report?

1. – Plan
2. – Organize the material
3. – Write
4. – Evaluate
5. – Rewrite

Whatever is the language of the inspection,
the report must be written in **English**

Report's Content

Summary Report

.

Checklist

.

SUMMARY REPORT

Contents

SUMMARY REPORT

Section A. General Information & Overview

Programme/Institution name:	
City:	
Country:	
Type of inspection:	Initial / Reaccreditation / Reinspection [*delete as necessary*]

Inspection date:	*DD-DD/MM/YYYY*	**Date of Inspection Report:**	*DD/MM/YYYY*	**Date of Summary Report:**	*[DD/MM/YYYY for office use only]*

Edition of standards used for inspection:	5th

Accreditation goal *(delete as appropriate)*:

Area	Patient	Allogeneic	Autologous
Clinical	Adult	X	X
	Paediatric	X	X
HPC, Marrow Collection	Adult	X	X
	Paediatric	X	X
HPC, Apheresis Collection	Adult	X	X
	Paediatric	X	X
Processing	-	X	X

Directors *(complete all sections)*

	Clinical (Adults)	Clinical (Paediatrics)	HPC(M) Collection	HPC(A) Collection	Cell Processing
Director					
Medical Director					

Include other information about Directors if necessary:

Information on the Programme

SUMMARY REPORT

Inspectors:	
Team Leader:	
Clinical Facility(s):	
HPC, Marrow Collection Facility	
HPC, Apheresis Collection Facility:	
Processing Facility:	
Quality Manager:	
Observer(s) and their organisation	-

Information on the inspection team

Services provided to other facilities not inspected during this audit:
[Complete this where the inspector is aware of any other relationships with facilities not part of this application e.g. registries, other hospitals. *If none, mark as 'N/A'.]*

Observations on the interaction between clinical, collection and processing facilities:	
[Reflect on what evidence you saw of interaction and communication between the different facilities]	
Distance between facilities (if possible, please describe the distance, duration and mode e.g. 5km, 10 mins, by car)	
Collection Facility(s) to Clinical Unit(s)	
Collection Facility(s) to Processing Facility	
Processing Facility(s) to Clinical Unit(s)	

Additional remarks:

Other information on the Centre

SUMMARY REPORT

Section B. Team Leader On-site Inspection Summary

Team Leader On-site Inspection Summary:
[Use this section to describe the inspection. Describe the atmosphere, any incidents that came up, and the overall impression of the programme. This last point is sometimes called the "helicopter view" and means to consider all aspects together and not just as individual elements. The FACT-JACIE standards emphasize the total programme and the interactions in place between the different services. *Each individual inspector should describe the facility(s) he/she has visited in their respective section of this report.* *Again, specific elements or deficiencies should be detailed in the Inspection Checklist]*

Team leader overview

SUMMARY REPORT

Cellular Therapy Product Administration & Clinical Facilities	
Persons interviewed during the Inspection	
Name	**Position/role**
	Programme Director Transplant physician/Consultant/Specialist Physician in training Quality manager Senior Nurse Nurses in training (or newest nurse in the unit) Other BMT unit nurses Pharmacist *[insert or delete positions as necessary]*

Names & Roles of people you interviewed

Numbers of transplants for 12 months up to inspection date		
	Allogeneic	**Autologous**
Adults	*[This section should be completed]*	*[This section should be completed]*
Paediatrics	*[This section should be completed]*	*[This section should be completed]*

Brief description of facility(s) inspected:
[Limit the description to the unit e.g. how long it has been established, populatio… …s with other organisations, etc. but not specific deficiencies or observations. These should be … …tion Checklist]

Main Strengths & Areas for Improvement	
Strengths	○ *[This section should be for general …ggestio… should be detailed in the Inspection Checklist]*
Areas for improvement	○ *[This section should be for general suggestions. Spe… should be detailed in the Inspection Checklist]*

REMEMBER!

SUMMARY REPORT

CM7, C7 & D7 Labels (Cell Collection & Cell Processing)

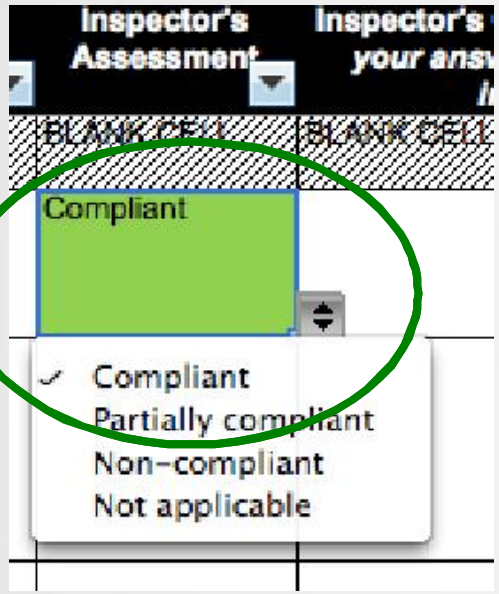
Inspector who performed check	Area
	HPC(M)
	HPC(A)
	Processing

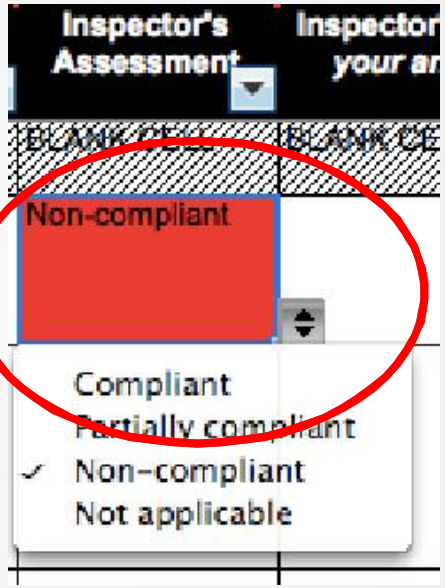
CHECKLIST

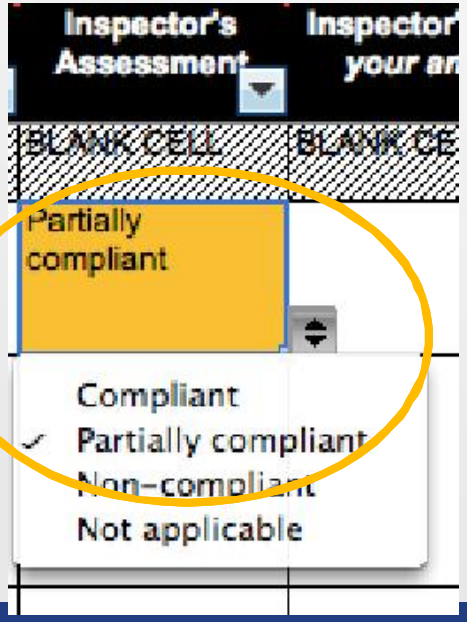
Ref	Standard	Applicant's Self-assessment	Applicant's Comments *(support your answers with additional information)*	Inspector's Assessment	Inspector's Comments *(support your answers with additional information)*	Accreditation Committee comments	Applicant's corrections & comments
D03	PERSONNEL						
D03.01	PROCESSING FACILITY DIRECTOR						
D03.01.01	There shall be a Processing Facility Director who is an individual with a medical degree or doctoral degree in a relevant science, qualified by training or experience for the scope of activities carried out in the Processing Facility. The Processing Facility Director may also serve as the Processing Facility Medical Director, if appropriately credentialed.	Compliant	LABTMO-SOP-08	Compliant	PROC PRC TRA 06.07.85		
D03.01.02	The Processing Facility Director shall be responsible for all procedures, administrative operations, and the Quality Management Program of the Processing Facility, including compliance with these Standards and other applicable laws and regulations.	Compliant	LABTMO-SOP-08	Compliant	PROC PRC TRA 06.07.85		
D03.01.03	The Processing Facility Director shall participate regularly in educational	Compliant	LABTMO-SOP-08	Compliant	PROC PRC TRA		

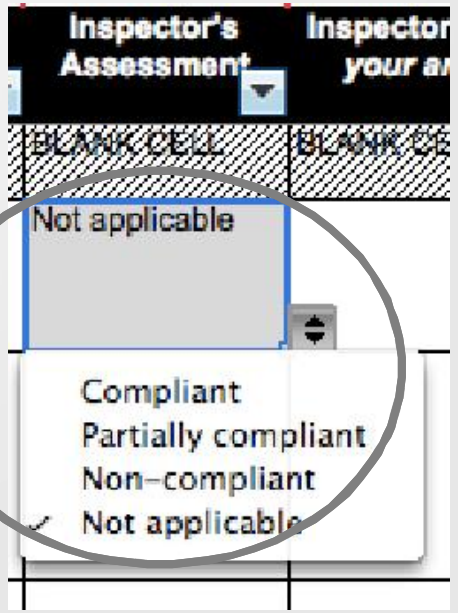
... | Part B Clinical | Part B MED-A audit forms | B-CM-C 6 Donors | Part CM Marrow | Part C Apheresis | Part D Processing | All Labels Con

CHECKLIST


Inspector's Assessment
Compliant
Compliant
Partially compliant
Non-compliant
Not applicable


Inspector's Assessment
Non-compliant
Compliant
Non-compliant
Not applicable


Inspector's Assessment
Partially compliant
Compliant
Partially compliant
Not applicable


Inspector's Assessment
Not applicable
Compliant
Partially compliant
Non-compliant
Not applicable

CHECKLIST

Ref.	Standard	Applicant's assessment	Source of evidence and explanatory text	Inspector's Assessment	Inspector's Comments *(support your answers with additional information)*
B.04.04.02.03	Initial training and retraining when appropriate for all procedures performed.	Compliant	No evidence	Partially compliant	Lack for description of descripton of activities regarding initial training because they do not preview actually any new person in the staff

Clarify any answers using the Comments column

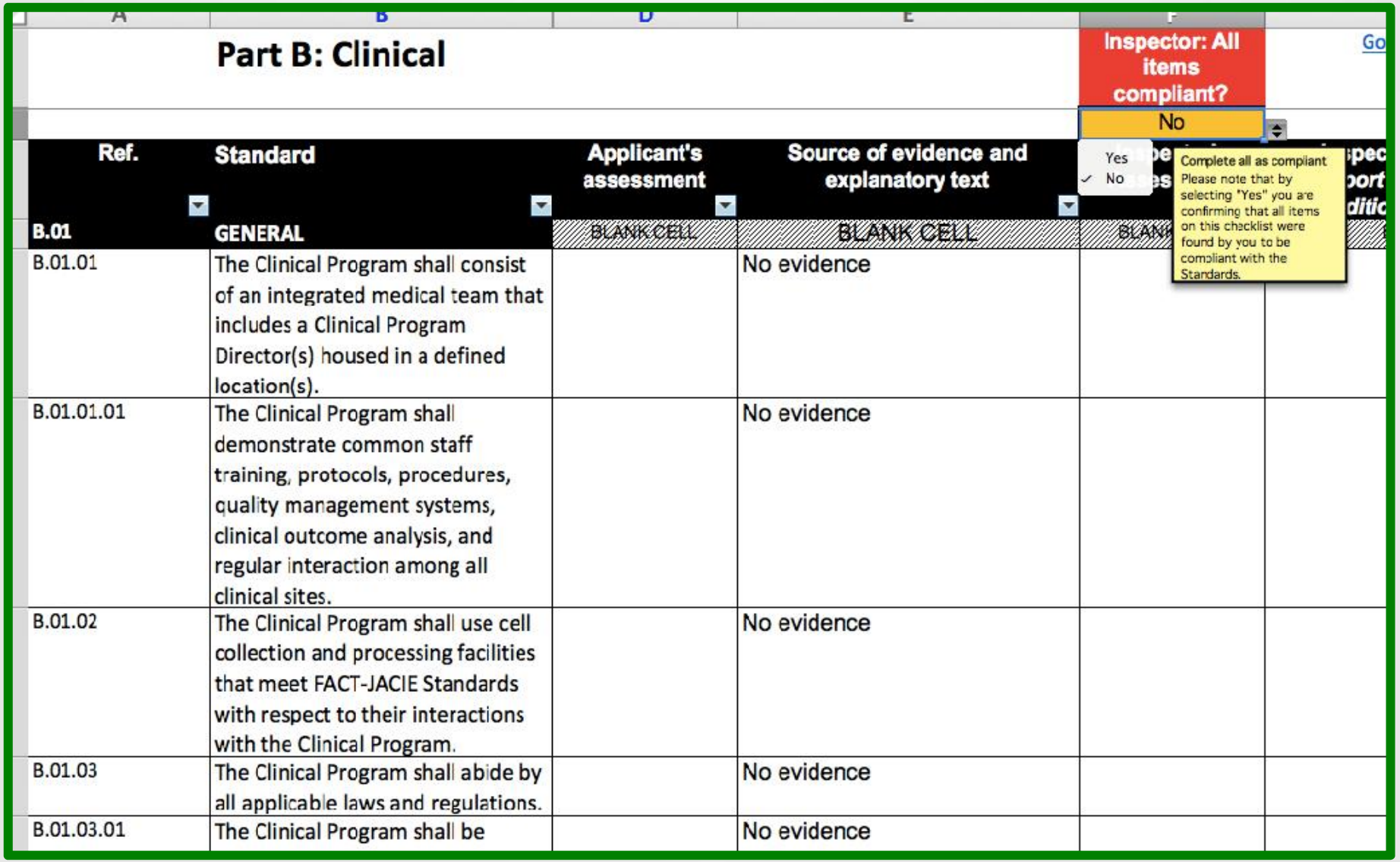
CHECKLIST

Type of label	Standard	Cat.	Applicant's assessment	Source of evidence and explanatory text	Inspector's Assessment	Inspector's Comments (support your answers with additional information)	Accreditation Com
Label at completion of collection	Unique numeric or alphanumeric identifier	AF		No evidence			
Label at completion of collection	Proper name of product	AF		No evidence			

QM-Part CM | Part C Apheresis | QM - Part C | Part D Processing | QM - Part D | Labels-Collection | Labels-Processing | Shipping & Transport

Remember to complete the labels section

CHECKLIST



Ref.	Standard	Applicant's assessment	Source of evidence and explanatory text	Inspector: All items compliant?
B.01	**GENERAL**	BLANK CELL	BLANK CELL	BLANK
B.01.01	The Clinical Program shall consist of an integrated medical team that includes a Clinical Program Director(s) housed in a defined location(s).		No evidence	
B.01.01.01	The Clinical Program shall demonstrate common staff training, protocols, procedures, quality management systems, clinical outcome analysis, and regular interaction among all clinical sites.		No evidence	
B.01.02	The Clinical Program shall use cell collection and processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Clinical Program.		No evidence	
B.01.03	The Clinical Program shall abide by all applicable laws and regulations.		No evidence	
B.01.03.01	The Clinical Program shall be		No evidence	

CHECKLIST

				Items compliant?
				Yes
Ref.	**Standard**	**Applicant's assessment**	**Source of evidence and explanatory text**	**Inspector's Assessment**
B.01	**GENERAL**	BLANK CELL	BLANK CELL	BLANK CELL
B.01.01	The Clinical Program shall consist of an integrated medical team that includes a Clinical Program Director(s) housed in a defined location(s).		No evidence	Compliant
B.01.01.01	The Clinical Program shall demonstrate common staff training, protocols, procedures, quality management systems, clinical outcome analysis, and regular interaction among all clinical sites.		No evidence	Compliant
B.01.02	The Clinical Program shall use cell collection and processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Clinical Program.		No evidence	Compliant
B.01.03	The Clinical Program shall abide by		No evidence	

CHECKLIST

Cover | Instructions | Snapshot | Dashboard | Part B Clinical | QM-PartB | Part B MED-A audit forms | Part CM Bone Marrow | QM-Part CM | B-CM-C 6 Donors | Part C Apheresis | QM - Part C

- Cover
- Snapshot

- Instructions
- Dashboard
- Definitions
- Appendix I–Min transplants
- Appendix II–CT Labeling
- Appendix III–Labels for shipping
- Appendix IV–Docs at distribution

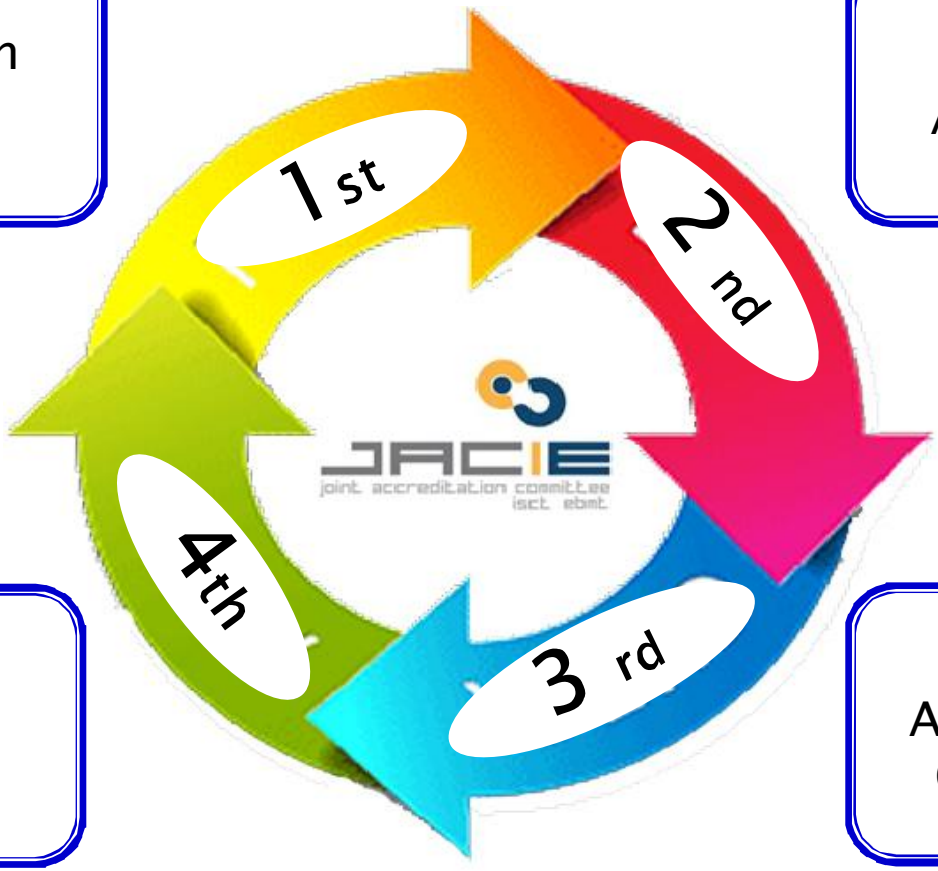
- Part B Clinical
- QM – Part B
- Part B Med–A audit forms
- Part CM Bone Marrow
- QM – Part CM
- Part C Apheresis
- QM – Part C
- Part D Processing
- QM – Part D
- Labels–Collection
- Labels – Processing
- Shipping & Transport

Part D Processing | QM - Part D | Labels-Collection | Labels-Processing | Shipping & Transport | Appendix I-Min transplants | Appendix II-CT Labelling | Appendix III-Labels for ship. | Appendix IV-Docs at distrib. | Definitions

Report pathway

Inspection Team

Report Assessors



Center

JACIE Accreditation Committee

JACIE joint accreditation committee isct ebmt

European Society for Blood and Marrow Transplantation

EBMT

International Society for Cellular Therapy

ISCT

Thank you for your attention
Questions or comments welcome