IMPUTABILITY GRADE	CRITERIA FOR INFECTIOUS AND MALIGNANT TRANSMISSIONS ADAPTED FROM DTAC (1)	ADAPTED FROM EUSTITE-SOHO V&S (2) AND PROPOSED STANDARD DEFINITIONS FOR SURVEILLANCE OF NON INFECTIOUS ADVERSE TRANSFUSION REACTIONS (3)	ADAPTED FROM EUSTITE - SOHO V&S IN ASSISTED REPRODUCTIVE TECNOLOGIES (2)
Not Assessable	Insufficient data for imputability assessment	Insufficient data for imputability assessment	Insufficient data for imputability assessment
Excluded	**Suspected transmission and fulfillment of at least one of the following conditions:** - Clear evidence of an alternative cause; - The appropriate diagnostic tests performed have failed to document infection by the same pathogen in any recipient from the same donor; Laboratory evidence that the recipient was infected with the same pathogen or had a tumor before the application of organs, tissues or cells.	Conclusive evidence beyond reasonable doubt that the adverse occurrence can be attributed to causes other than the transfusion of blood components or transplantation of tissues/cells	Conclusive evidence beyond reasonable doubt for attributing to alternative causes than the ART process
Possible	**Suspected transmission and:** - Laboratory evidence of the pathogen or tumor in a single recipient, **or** **Suspected transmission and:** - Laboratory evidence of the pathogen or tumor in a single recipient or - Data suggest a transmission but are insufficient to confirm it.	The evidence is indeterminate for attributing the adverse occurrence either to the quality/safety of tissues/cells/blood components (for recipients), to the donation process (for donors), or to alternative causes	Evidence is indeterminate

Likely/Probable	**The following two conditions are met:** - Suspected transmission and - Laboratory evidence of the pathogen or the tumor in a recipient. **And it meets at least one of the following conditions:** - Laboratory evidence of the same pathogen or tumor in other recipients; - Laboratory evidence of the same pathogen or tumor in the donor; If there is pre-transplant laboratory evidence, such evidence must indicate that the same recipient was negative for the pathogen involved before transplantation.	The evidence is clearly in favour of attributing the adverse occurrence to the quality/safety of tissues/cells/blood components (for recipients) or to the donation process (for donors)	The evidence is in favour of attributing to the ART process
Definite/Certain; Proven	**All the following conditions are met:** - Suspected transmission; - Laboratory evidence of the pathogen or the tumor in a recipient; - Laboratory evidence of the same pathogen or tumor in other recipients (if multiple recipients); - Laboratory evidence of the same pathogen or tumor in the donor; - If there is a pre-transplant laboratory evidence, it should be noted that the same recipient was negative for the pathogen before transplantation	The evidence is conclusive beyond reasonable doubt for attributing the adverse occurrence to the quality/safety of tissues/cells/ blood components (for recipients) or to the donation process (for donors)	Conclusive evidence beyond reasonable doubt for attributing to the ART process

(1) An Update on Donor-Derived Disease Transmission in Organ Transplantation, M. G. Ison, and M. A. Nalesnik. American Journal of Transplantation 2011; 11: 1123–1130

(2) SOHO V&S Guidance for Competent Authorities: Communication and Investigation of Serious Adverse Events and Reactions associated with Human Tissues and Cells http://www.notifylibrary.org/sites/default/files/SOHO%20V%26S%20Communication%20and%20Investigation%20Guidance.pdf

(3) Proposed standard definitions for surveillance of non infectious adverse transfusion reactions, incorporating correction to TRALI definition (as adopted June 2013). ISBT Working Party on Haemovigilance http://www.notifylibrary.org/sites/default/files/Proposed%20Definitions%20for%20surveillance%20of%20non%20infectious%20adverse%20transfusion%20reactions%202011-2013_0.pdf