Aggiornamento e applicazione degli standard JACIE in Italia

Argomenti

- JACIE background
- Aggiornamento sugli standard
- L’accreditamento JACIE in Italia

JACIE background

JACIE - Obiettivi

- Promuovere la qualità nella raccolta e nella manipolazione delle CSE e nella cura dei pazienti sottoposti a trapianto grazie ad un processo di accreditamento riconosciuto a livello internazionale
- Fornire uno strumento attraverso il quale un Centro possa dimostrare il proprio livello di qualità rispetto a standard di eccellenza condivisi
- Favorire la collaborazione fra Paesi con lingue e culture diverse al fine di realizzare un comune percorso di accreditamento
- Fornire percorsi di formazione per i futuri ispettori e per i Centri (gestione degli audit interni, gestione del sistema qualità)

FACT-JACIE relationship

- ✓ FACT developed standards in mid-1990's
- ✓ Developing interest in standards among European transplanters in late 1990's
- ✓ JACIE provided input to 2nd edition of Standards e.g. paediatric requirements
- ✓ Closer cooperation on 3rd and 4th editions. Introduced more global terminology
- ✓ 5th edition will see equal European and North American representation

Regulations

France

- Engagement with JACIE a requirement for allogeneic transplant centres
- Arrêté du 3 avril 2009 relatif au contenu du document d'évaluation des activités de greffes d'organes et de greffes de cellules hématopoïétiques.21 abril 2009 - Edition numéro 0093, Journal Officiel de la Republique Francaise

Switzerland

- Accreditation required to receive reimbursement from Social Insurance for treatments

The Netherlands

- Accreditation required to receive authorisation to transplant from Ministry of Health
- 25 October 2006 Regeling stamceltransplantatie

Guidelines

United Kingdom

- JACIE cited in National Institute for Health and Clinical Excellence (NICE) guidelines October 2003 Improving Outcomes in Haematological Cancers: The Manual

Collaborations

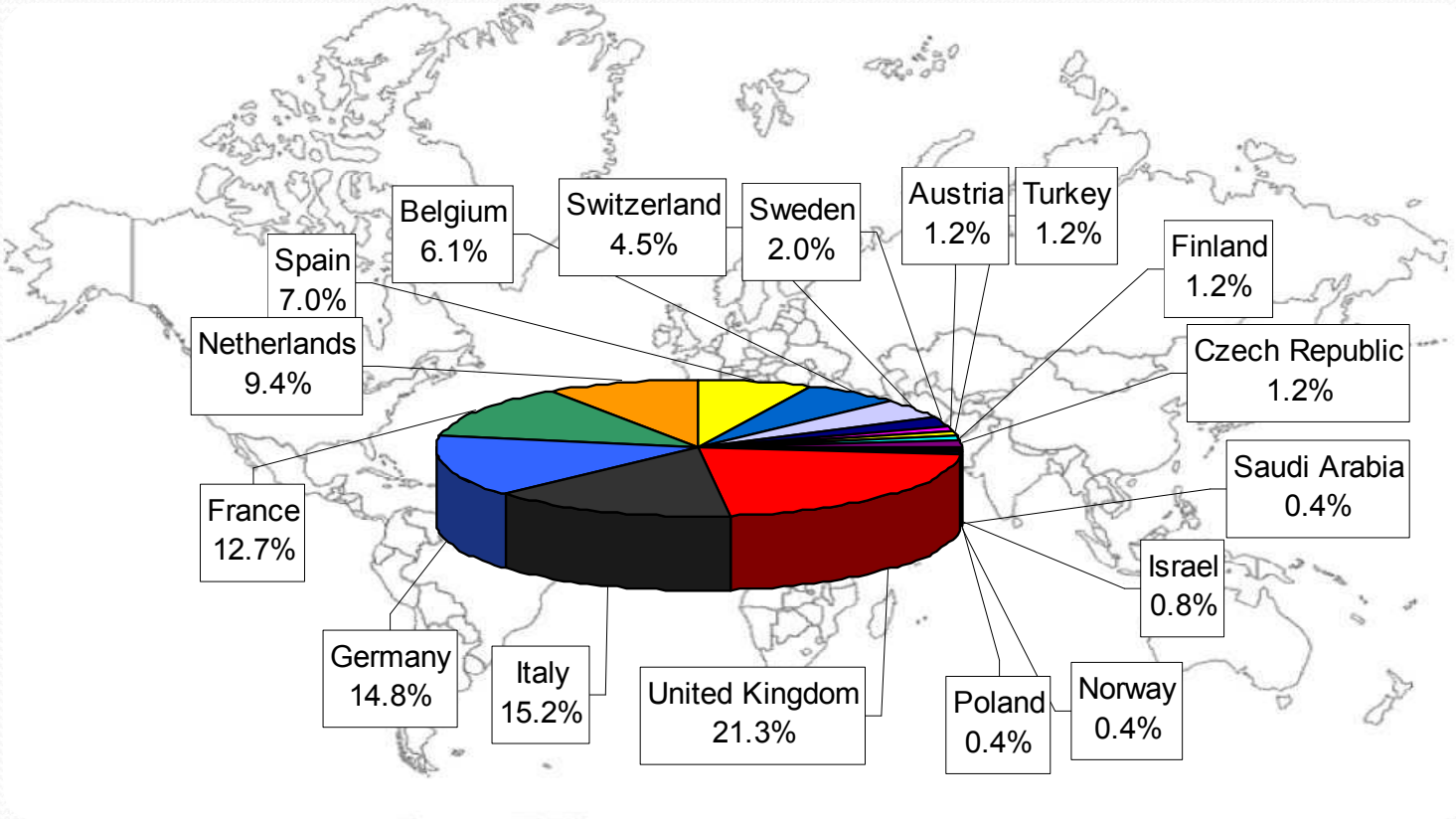
Italy

- Centro Nazionale de Trapianti (CNT) has coordinated inspections of Italian centres with JACIE through GITMO.

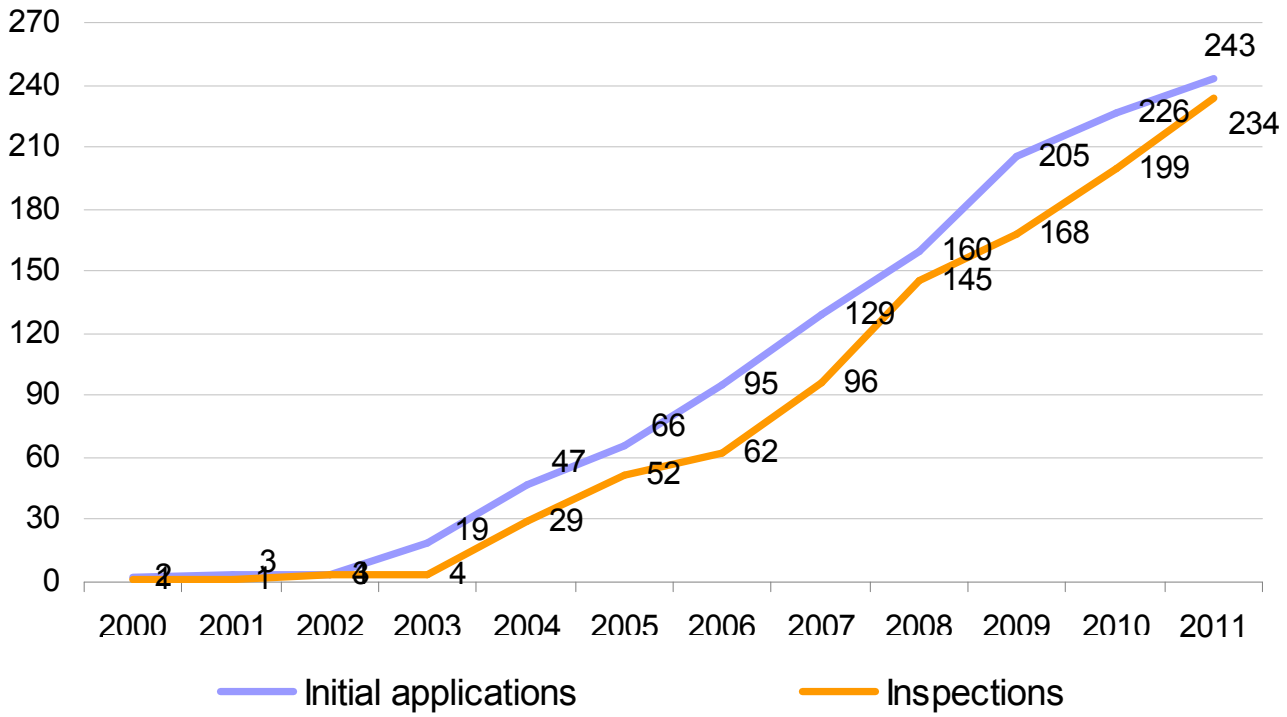
Spain

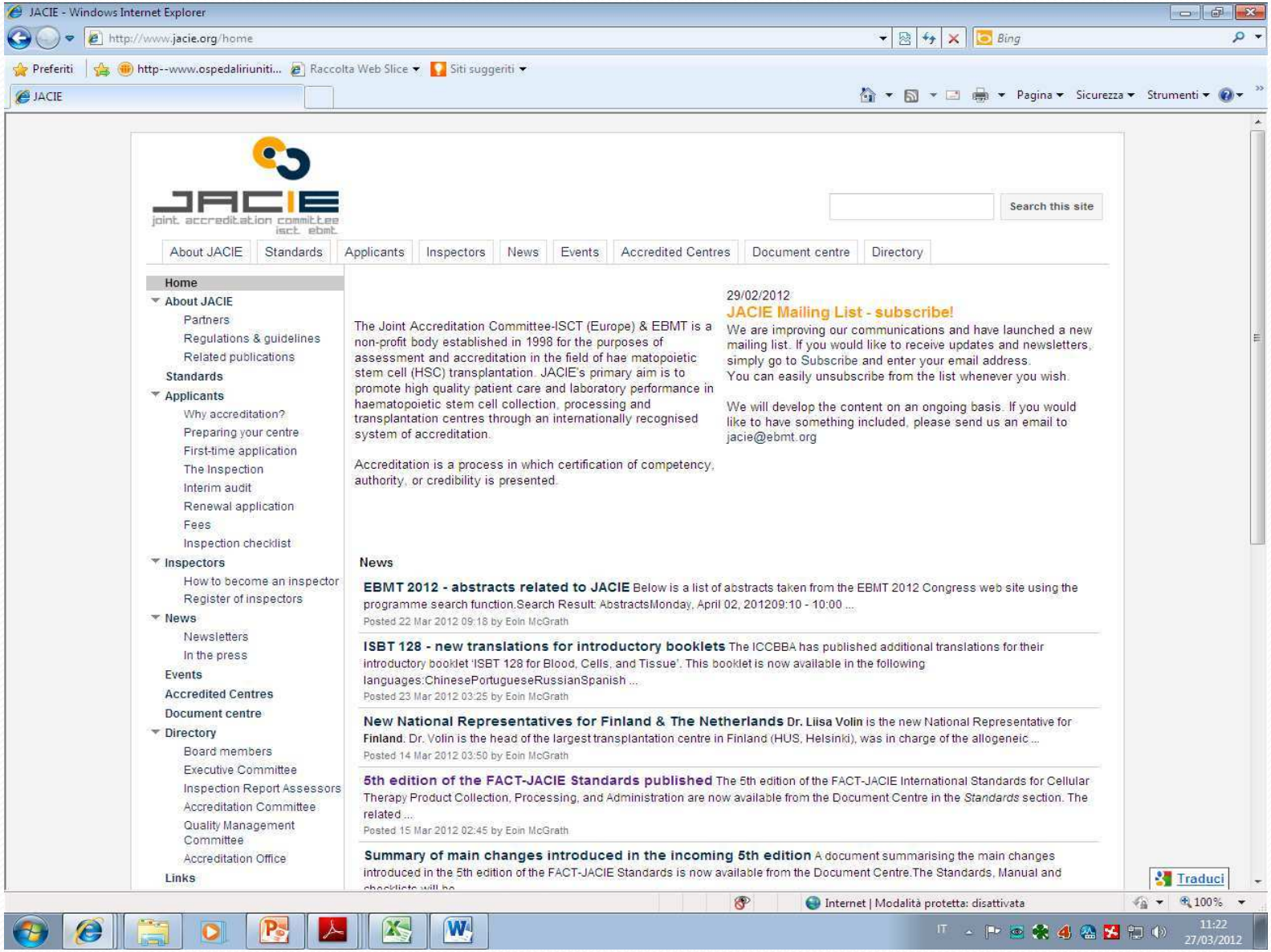
- Collaboration project with the National Transplant Organisation (ONT) and the Transfusion Accreditation Committee (CAT) under the name Comité Conjunto de Acreditación (CCA).

% distribution of total initial applications by country



Cumulative initial applications and all inspections




JACIE - Windows Internet Explorer
http://www.jacie.org/home
Bing
Preferiti
http--www.ospedaliriuniti...
Raccolta Web Slice
Siti suggeriti
JACIE
Pagina
Sicurezza
Strumenti
joint accreditation committee isct ebmt
Search this site
About JACIE
Standards
Applicants
Inspectors
News
Events
Accredited Centres
Document centre
Directory
Home
About JACIE
Partners
Regulations & guidelines
Related publications
Standards
Applicants
Why accreditation?
Preparing your centre
First-time application
The Inspection
Interim audit
Renewal application
Fees
Inspection checklist
Inspectors
How to become an inspector
Register of inspectors
News
Newsletters
In the press
Events
Accredited Centres
Document centre
Directory
Board members
Executive Committee
Inspection Report Assessors
Accreditation Committee
Quality Management Committee
Accreditation Office
Links
The Joint Accreditation Committee-ISCT (Europe) & EBMT is a non-profit body established in 1998 for the purposes of assessment and accreditation in the field of hae matopoietic stem cell (HSC) transplantation. JACIE's primary aim is to promote high quality patient care and laboratory performance in haematopoietic stem cell collection, processing and transplantation centres through an internationally recognised system of accreditation.
Accreditation is a process in which certification of competency, authority, or credibility is presented.
29/02/2012
JACIE Mailing List - subscribe!
We are improving our communications and have launched a new mailing list. If you would like to receive updates and newsletters, simply go to Subscribe and enter your email address.
You can easily unsubscribe from the list whenever you wish.
We will develop the content on an ongoing basis. If you would like to have something included, please send us an email to jacie@ebmt.org
News
EBMT 2012 - abstracts related to JACIE Below is a list of abstracts taken from the EBMT 2012 Congress web site using the programme search function.Search Result: AbstractsMonday, April 02, 201209:10 - 10:00 ...
Posted 22 Mar 2012 09:18 by Eoin McGrath
ISBT 128 - new translations for introductory booklets The ICCBBA has published additional translations for their introductory booklet 'ISBT 128 for Blood, Cells, and Tissue'. This booklet is now available in the following languages:ChinesePortugueseRussianSpanish ...
Posted 23 Mar 2012 03:25 by Eoin McGrath
New National Representatives for Finland & The Netherlands Dr. Liisa Volin is the new National Representative for Finland. Dr. Volin is the head of the largest transplantation centre in Finland (HUS, Helsinki), was in charge of the allogeneic ...
Posted 14 Mar 2012 03:50 by Eoin McGrath
5th edition of the FACT-JACIE Standards published The 5th edition of the FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration are now available from the Document Centre in the Standards section. The related ...
Posted 15 Mar 2012 02:45 by Eoin McGrath
Summary of main changes introduced in the incoming 5th edition A document summarising the main changes introduced in the 5th edition of the FACT-JACIE Standards is now available from the Document Centre.The Standards, Manual and
Traduci
Internet | Modalità protetta: disattivata
100%
11:22
27/03/2012

Uno strumento molto utile

- Scaricabile dal sito web: http://www.jacie.org
- Guida pratica all'implementazione di un sistema di gestione della qualità per un Programma di Trapianto di cellule staminali emopoietiche (con esempi di modulistica e procedure)

Aggiornamento sugli standard

…… la 5ª edizione


INTERNATIONAL STANDARDS FOR CELLULAR THERAPY PRODUCT COLLECTION, PROCESSING, AND ADMINISTRATION
ACCREDITATION MANUAL

FACT FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY AT THE UNIVERSITY OF NEBRASKA MEDICAL CENTER

JACIE joint accreditation committee ISCT - EBMT

Guidance to Accompany the
FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration, Fifth Edition

Fifth Edition
March 2012

- Disponibile da 1 marzo 2012
- Separazione del Centro di Raccolta di Midollo Osseo dal Centro di raccolta di CSE da Sangue periferico; le nuove sezioni sono
  - B – Unità Clinica
  - CM- Centro di Raccolta di CSE da Midollo Osseo
  - C – Centro di Raccolta di CSE da sangue periferico
  - D – Laboratorio di Processazione

FACT - JACIE Standards: 5th ed

Clinical (B)	Collection (CM+C)	Processing (D)
General	General	General
Clinical Unit	(Marrow/Apheresis) Collection Facility	Processing Facility
Personnel	Personnel	Personnel
Quality Management	Quality Management	Quality Management
Policies and Procedures	Policies and Procedures	Policies and Procedures
Allogeneic and Autologous Donor Selection, Evaluation, and Management	Allogeneic and Autologous Donor Evaluation and Management	Process Controls
Therapy Administration	Coding and Labeling	Coding and Labeling
Clinical Research	Process Controls	Distribution
Data Management	Cellular Therapy Product Storage	Storage
	Cellular Therapy Product Transportation and Shipping	Transportation, Shipping, and Receipt
		Disposal
Records	Records	Records
	Direct Distribution to Clinical Program	

Quanti sono gli standard

Part	4th	5th
A – Definitions	134	140
B - Clinical	287	336
CM – Marrow		151
C – Apheresis	250	281
D – Processing	387	407
TOTAL	1058	1315

Caratteristiche degli standard

- Alcuni sono declinati in modo molto specifico
  - es. list of cognitive skills for physicians
- Altri sono più generici
  - es. “unit must minimise risk of airborne contamination.”
- La Guida descrive nel dettaglio gli standard e aiuta nell’interpretazione.
- NB molti standard devono essere interpretati dall’ispettore
  - es. adequacy of staff numbers

Changes made to the 5th edition Cellular Therapy Standards

- New Marrow Collection Facility Standards
- Reorganized Accreditation Manual: explanation, evidence, example
- ABO/Rh Testing
  a. Removed requirement for testing on the 1° day of collection or on the 1° product collected.
  b. Removed the requirement for autologous donors.
  c. Added testing of allogeneic recipients in clinical and collection.
  d. Added requirement for ABO and Rh testing on two independently collected samples.
  e. Added red cell antibody screening
- Critical Electronic Record Systems (definition, explanation, examples)

Changes made to the 5th edition Cellular Therapy Standards

- Cord Blood Administration
- Allogeneic Donor Advocacy
- ISBT 128 terminology and other Labeling Changes
- Transport on Public Roads
- Appendix IV Removed
- Extracorporeal Photopheresis
- Quality Management
  annual report, document control, written agreements, deviations, interruption of operations

Changes made to the 5th edition Cellular Therapy Standards

- Policies and procedures
- Communicable Disease Testing
- Other Donor Evaluation and Testing
- Donor Suitability and Conflict of Interest
- Minimum Transplant Volumes
- Clinical Unit (ICU)
- Clinical Program Director
- Physician competency and other personnel (QM Supervisor)

Changes made to the 5th edition Cellular Therapy Standards

- Clinical Quality management
- Outcome analysis (overall and treatment-related mprbidity and mortality; 100 days post Tx; 1 year post Tx)
- Audits
- Written criteria for Donors
- Collection personnel
- Collection Quality management and process controls
- Laboratory Testing controls
- Expansion

Accreditamento JACIE in Italia

Ispezioni JACIE – CNT/CNS

team JACIE

Clinical, Collection and Processing facility inspectors

team CNT/CNS

Ispettore per centro di raccolta, per istituto dei tessuti

Condivisione dei rilievi e dei dubbi durante l'ispezione, ma redazione di due report distinti

NB Unico ispettore in solitaria.....nella Unità Clinica (non coperta dalla normativa di riferimento)

Ispezioni JACIE – CNT/CNS

Standard e normativa di riferimento

- ✓ Standard JACIE 5th edition
- ✓ Conferenza Stato – Regioni 10/7/2003
- ✓ D.Leg. 191/2007 e D.Leg. 16/2010

Normativa trasfusionale vigente, ove applicabile

- ✓ DM 3/3/2005 (1 e 2), D.Leg.261/2007, D.Leg. 208/2007, D.Leg. 207/2007

Linee Guida

- ✓ Linee guida per la raccolta di CSE nel donatore familiare e non familiare per trapianto allogenico (CNT)
- ✓ Raccomandazioni SIMTI – GITMO per la gestione della donazione di CSE nel donatore familiare e non familiare per trapianto allogenico

Formazione Ispettori

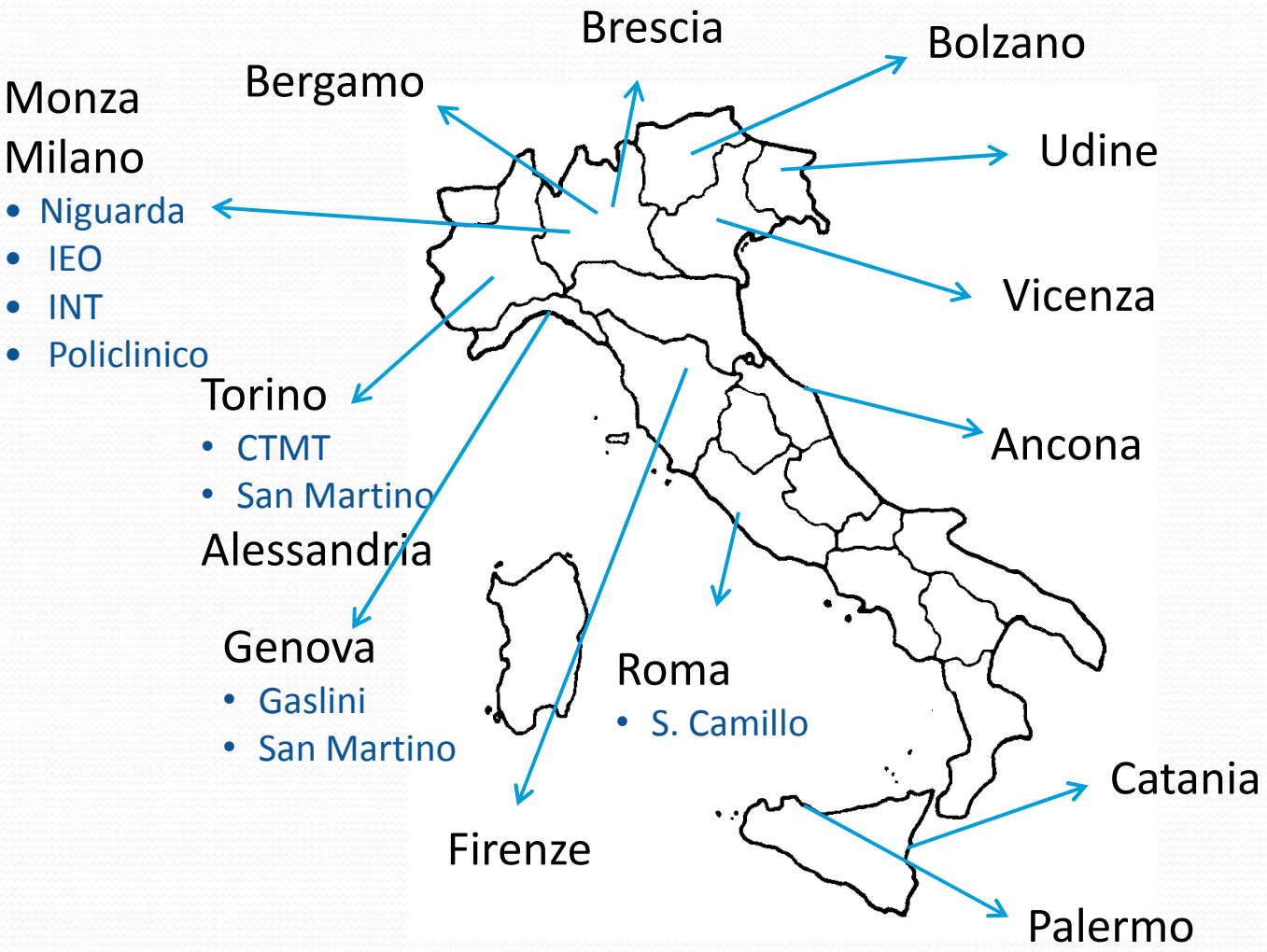
Ispettori JACIE formati mediante corsi internazionali ad hoc organizzati in diverse sedi europee

Ispettori CNT/CNS formati mediante corsi dedicati alla normativa di riferimento italiana

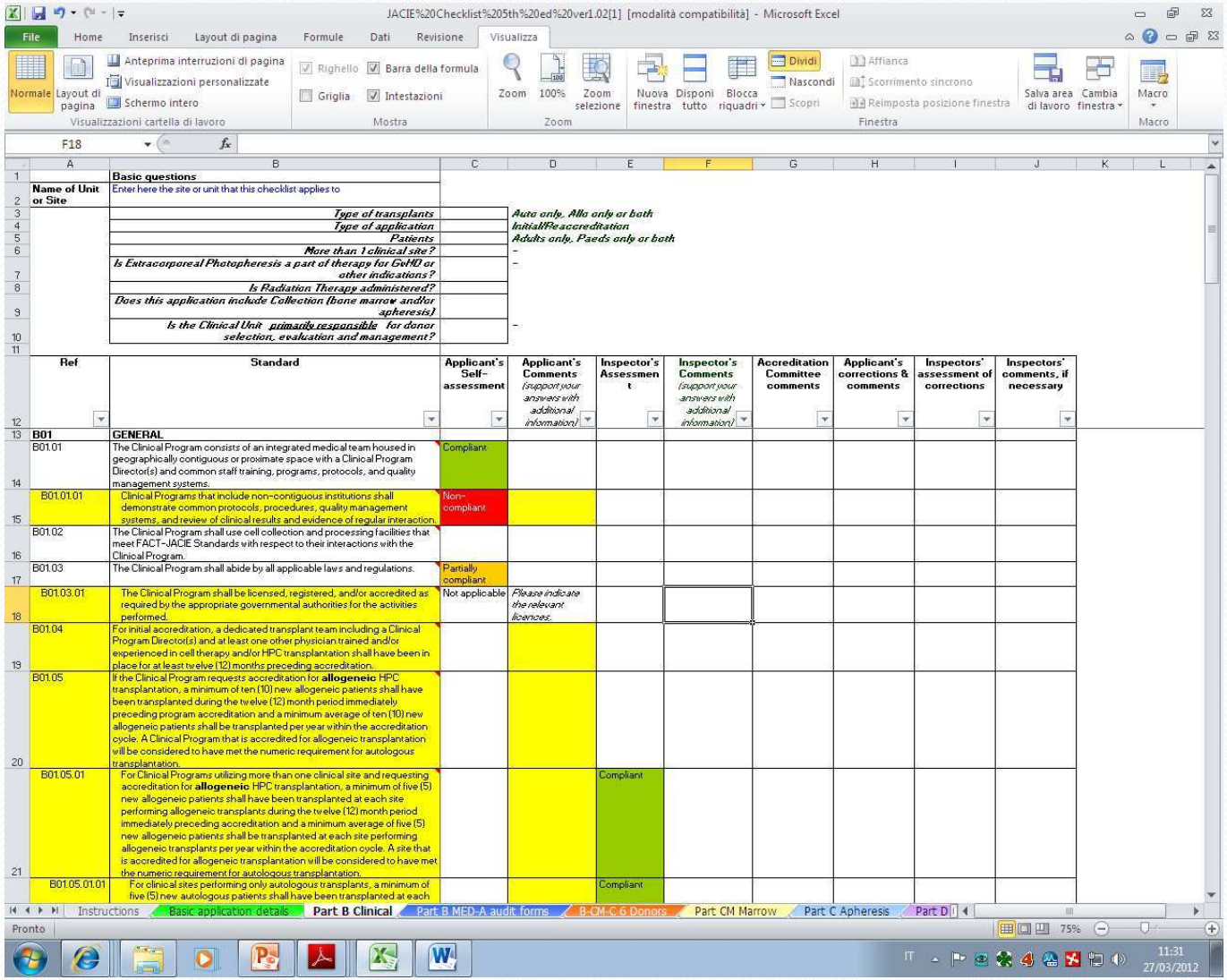
Novità

Nel 2011 primo corso comune per ispettori CNT/CNS e JACIE

Ispezioni JACIE – CNT/CNS



Inspection Checklist format



JACIE%20Checklist%205th%20ed%20ver1.02[1] [modalità compatibilità] - Microsoft Excel

	A	B	C	D	E	F	G	H	I	J	K	L
1		**Basic questions**										
2	**Name of Unit or Site**	Enter here the site or unit that this checklist applies to										
3		*Type of transplants*		*Auto only, Allo only or both*								
4		*Type of application*		*Initial/Re-accreditation*								
5		*Patients*		*Adults only, Paeds only or both*								
6		*More than 1 clinical site?*		–								
7		*Is Extracorporeal Photopheresis a part of therapy for GvHD or other indications?*		–								
8		*Is Radiation Therapy administered?*										
9		*Does this application include Collection (bone marrow and/or apheresis)*										
10		*Is the Clinical Unit primarily responsible for donor selection, evaluation and management?*		–								
11												
12	**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**	**Inspectors' assessment of corrections**	**Inspectors' comments, if necessary**		
13	**B01**	**GENERAL**										
14	B01.01	The Clinical Program consists of an integrated medical team housed in geographically contiguous or proximate space with a Clinical Program Director(s) and common staff training, programs, protocols, and quality management systems.	Compliant									
15	B01.01.01	Clinical Programs that include non-contiguous institutions shall demonstrate common protocols, procedures, quality management systems, and review of clinical results and evidence of regular interaction.	Non-compliant									
16	B01.02	The Clinical Program shall use cell collection and processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Clinical Program.										
17	B01.03	The Clinical Program shall abide by all applicable laws and regulations.	Partially compliant									
18	B01.03.01	The Clinical Program shall be licensed, registered, and/or accredited as required by the appropriate governmental authorities for the activities performed.	Not applicable	*Please indicate the relevant licences.*								
19	B01.04	For initial accreditation, a dedicated transplant team including a Clinical Program Director(s) and at least one other physician trained and/or experienced in cell therapy and/or HPC transplantation shall have been in place for at least twelve (12) months preceding accreditation.										
20	B01.05	If the Clinical Program requests accreditation for **allogeneic** HPC transplantation, a minimum of ten (10) new allogeneic patients shall have been transplanted during the twelve (12) month period immediately preceding program accreditation and a minimum average of ten (10) new allogeneic patients shall be transplanted per year within the accreditation cycle. A Clinical Program that is accredited for allogeneic transplantation will be considered to have met the numeric requirement for autologous transplantation.										
21	B01.05.01	For Clinical Programs utilizing more than one clinical site and requesting accreditation for **allogeneic** HPC transplantation, a minimum of five (5) new allogeneic patients shall have been transplanted at each site performing allogeneic transplants during the twelve (12) month period immediately preceding accreditation and a minimum average of five (5) new allogeneic patients shall be transplanted at each site performing allogeneic transplants per year within the accreditation cycle. A site that is accredited for allogeneic transplantation will be considered to have met the numeric requirement for autologous transplantation.			Compliant							
	B01.05.01.01	For clinical sites performing only autologous transplants, a minimum of five (5) new autologous patients shall have been transplanted at each			Compliant							

Instructions | Basic application details | Part B Clinical | Part B MED-A audit forms | B-CM-C & Donors | Part CM Marrow | Part C Apheresis | Part D

Pronto

75%

IT 11:31 27/03/2012

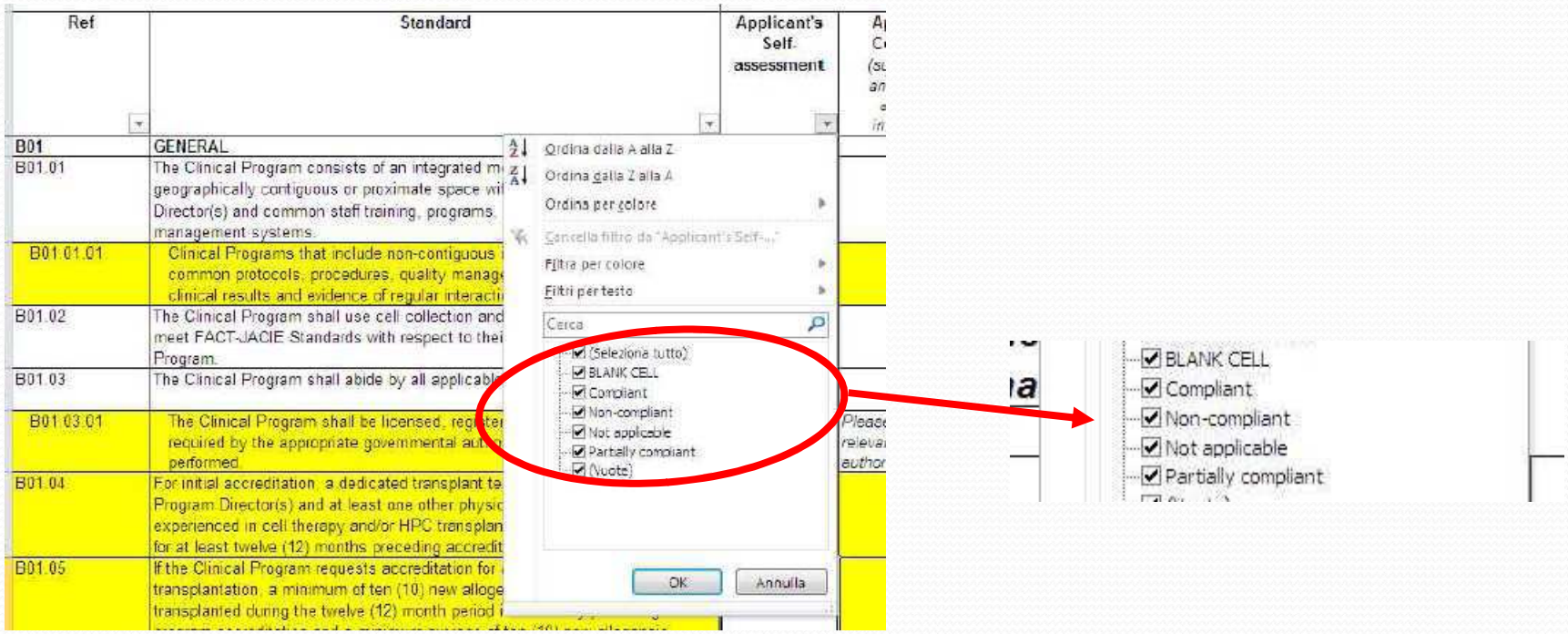
	Ref	Standard	Applicant's Self-assessment	Applicant's Comments *(support your answers with additional information)*	Inspector's Assessment	In… Co… *(su… ans… as… inf…*
12						
13	B01	GENERAL				
14	B01.01	The Clinical Program consists of an integrated medical team housed in geographically contiguous or proximate space with a Clinical Program Director(s) and common staff training, programs, protocols, and quality management systems	Compliant		Compliant	
15	B01.01.01	Clinical Programs that include non-contiguous institutions shall demonstrate common protocols, procedures, quality management systems, and review of clinical results and evidence of regular interaction	Partially compliant		Compliant Partially compliant Non-compliant Not applicable	
16	B01.02	The Clinical Program shall use cell collection and processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Clinical Program			Compliant	

Ora 4 risposte possibili

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)*
GENERAL				
The Clinical Program consists of an integrated medical team housed in geographically contiguous or proximate space with a Clinical Program Director(s) and common staff training, programs, protocols, and quality management systems	Compliant		Compliant	
Clinical Programs that include non-contiguous institutions shall demonstrate common protocols, procedures, quality management systems, and review of clinical results and evidence of regular interaction	Compliant		Partially compliant	
The Clinical Program shall use cell collection and processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Clinical Program			Non-compliant	
The Clinical Program shall abide by all applicable laws and regulations	Compliant		Not applicable	
The Clinical Program shall be licensed, registered, and/or accredited as	Non-compliant	Please indicate the	Compliant	

In caso di risposta “Partially compliant”, “non compliant” darne spiegazione

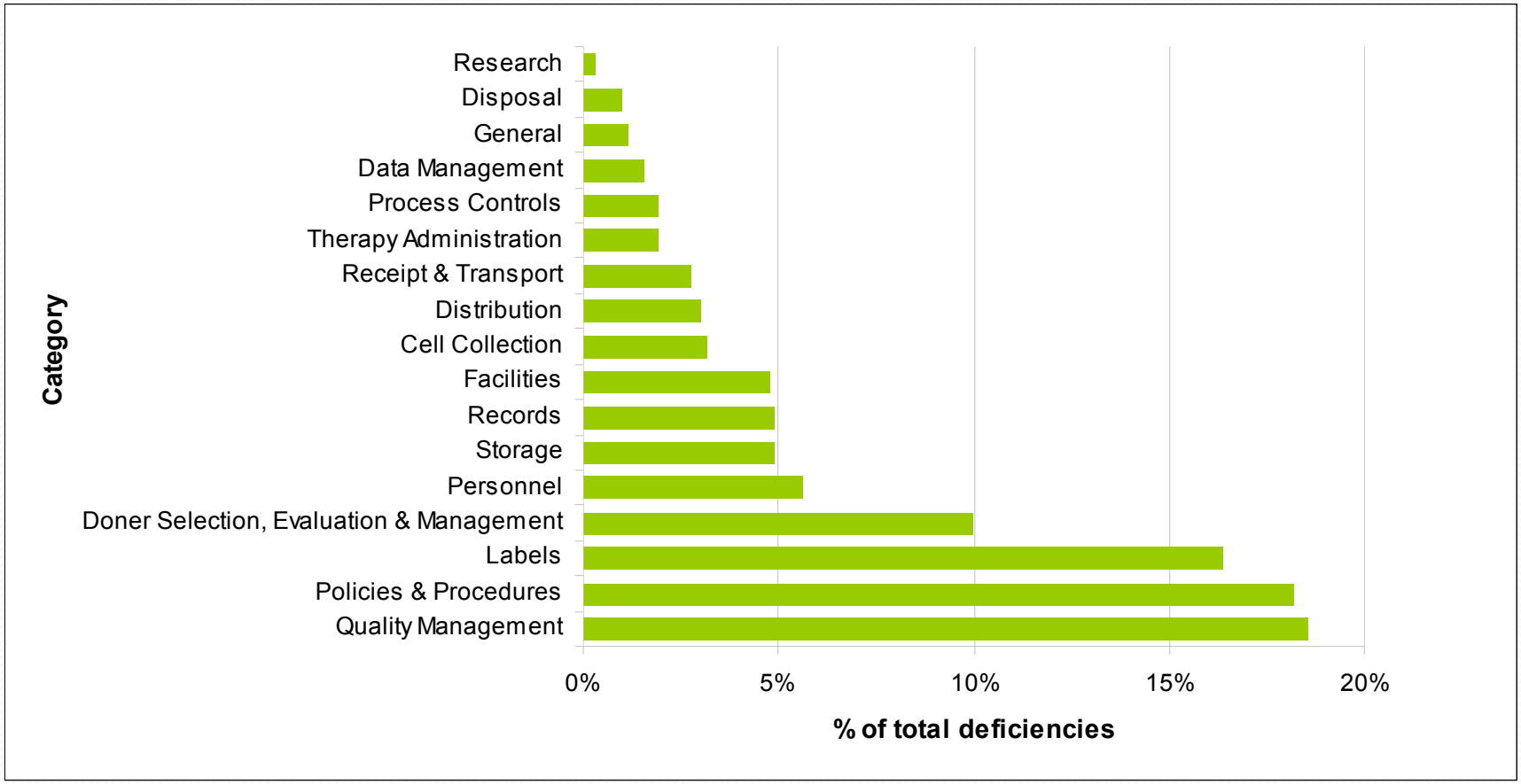
Il colore cambia in base alla risposta selezionata



Filtrare le risposte per verificare la completezza della checklist

Areas of deficiencies

Expressed as % of total deficiencies. Based on analysis of 1732 deficiencies encountered in inspections



Deviazioni minori vs maggiori

La differenza fra deviazioni minori e maggiori a volte è solo una questione di giudizio

- Deviazioni minori
  - modifica di procedure già esistenti
- Deviazioni maggiori- esempi
  - Inadeguato sistema di gestione dell'isolamento dei pazienti trapiantati
  - Carente monitoraggio della temperatura dei frigocongelatori
  - Sistema di gestione della qualità del Programma inadeguato

Interazioni fra le parti del Programma

- Il Centro di raccolta deve servirsi di Laboratori di processazione che ottemperino gli standard JACIE
- Il Centro di raccolta di CSE da Midollo osseo (spesso parte integrante dell'Unità Clinica) deve essere ispezionato e accreditato
- Il Centro di Raccolta di CSE da sangue periferico e il laboratorio di Processazione possono far parte del Programma o essere esterni

L'interazione fra le parti è fondamentale es.

- Richiesta di raccolta CSE scritta
- Comunicazione dei dati di engraftment al Centro di raccolta e al laboratorio di Processazione
- Comunicazione di AE alle parti del programma
- Convenzioni o contratti con centri o laboratori esterni al Programma

Conclusioni

Conclusioni

- L'accreditamento JACIE si sta diffondendo in Europa e viene sempre più riconosciuto come uno strumento di garanzia per i pazienti e per garantire i Sistemi Sanitari Nazionali e le Assicurazioni a riguardo della qualità delle prestazioni erogate
- L'organizzazione e la pratica clinica quotidiana traggono giovamento dai comportamenti virtuosi implementati grazie ad una gestione in qualità di una organizzazione complessa quale quella di un Programma di Trapianto
- Si stanno accumulando dati scientifici che suggeriscono come i programmi di trapianto accreditati hanno risultati clinici superiori