



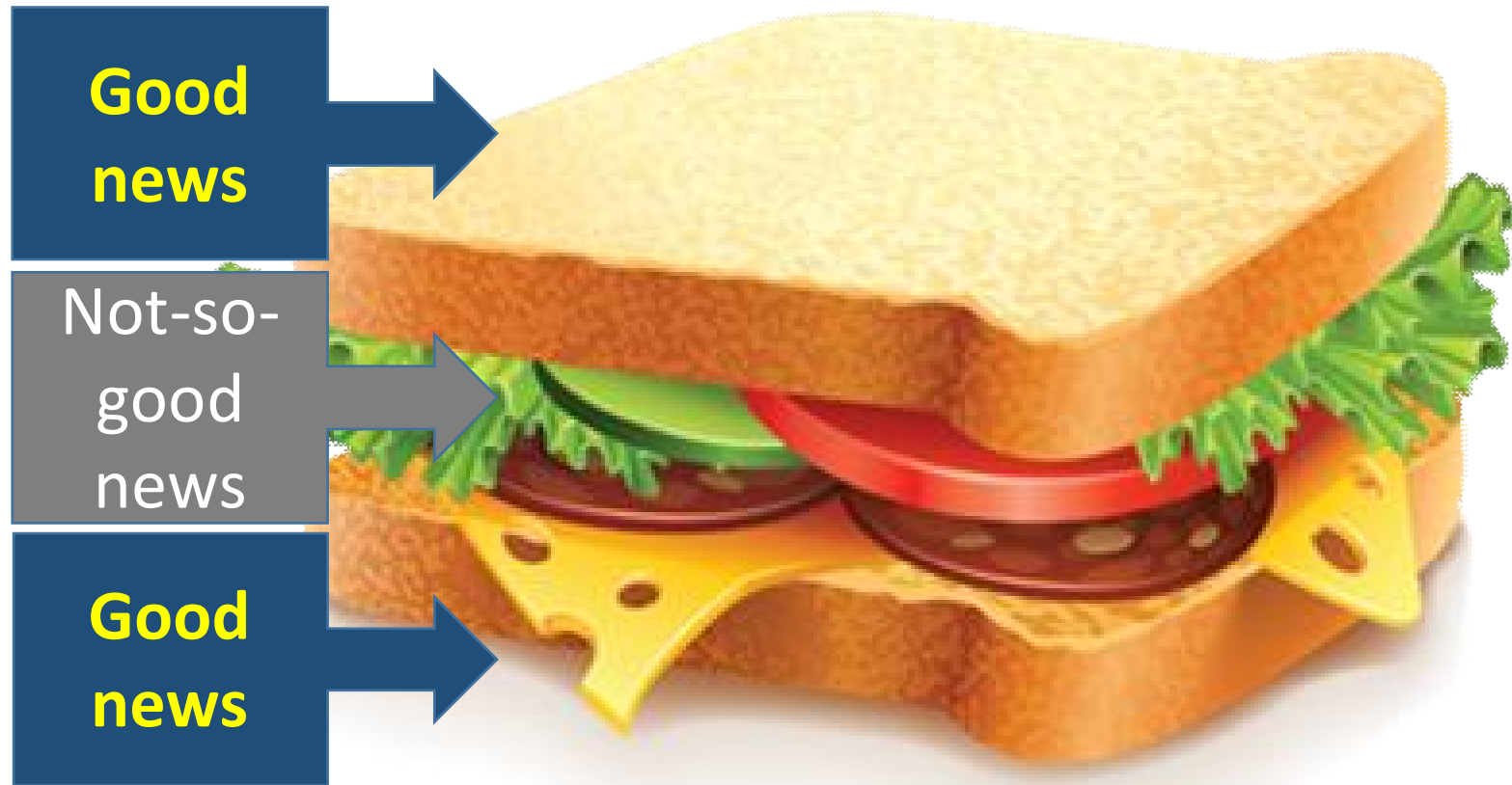
Experiencia en el programa JACIE en España.

Fortalezas y debilidades



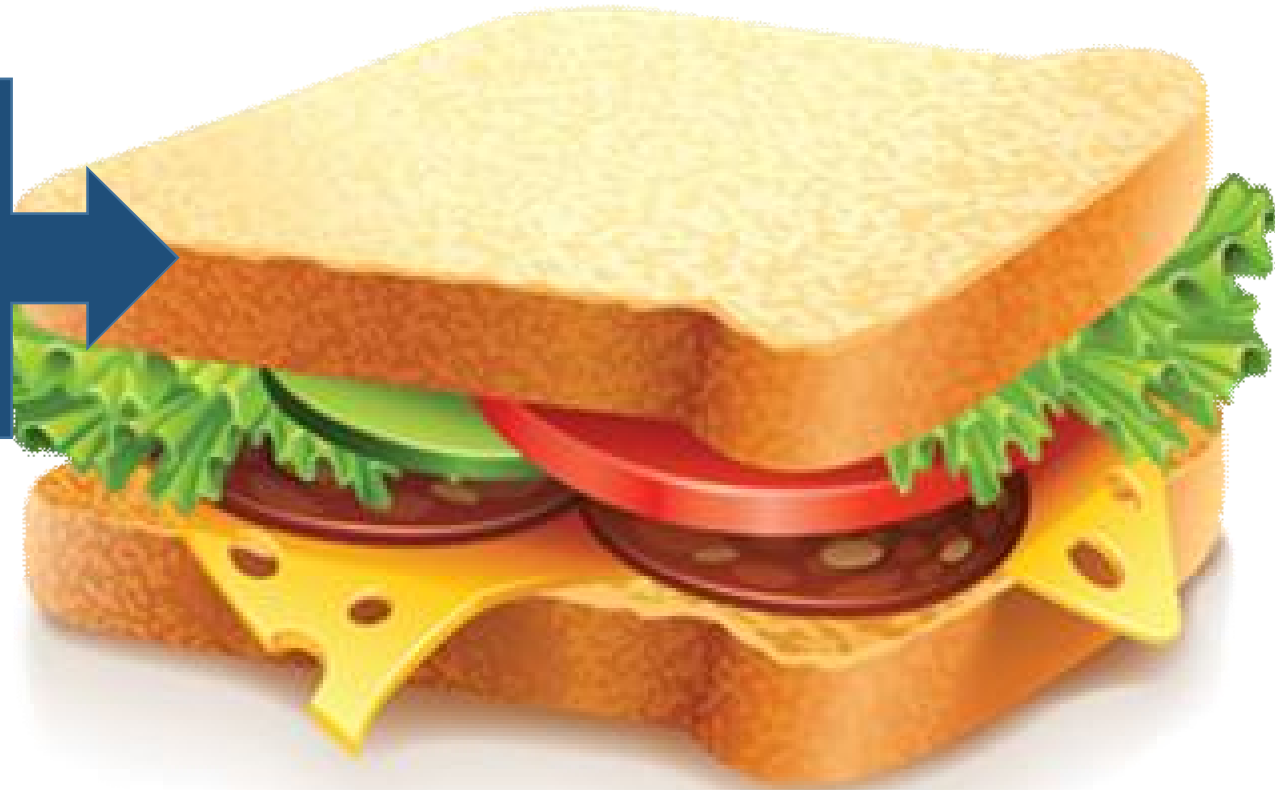
- Eoin McGrath
- JACIE Operations Manager, EBMT
- Desde 2002

'Good News Sandwich'



'Good News Sandwich'

**Good
news**



Historia

Primera inspección JACIE en **Europa** – Hospital Sant Pau, Barcelona



Pioneros en Europa

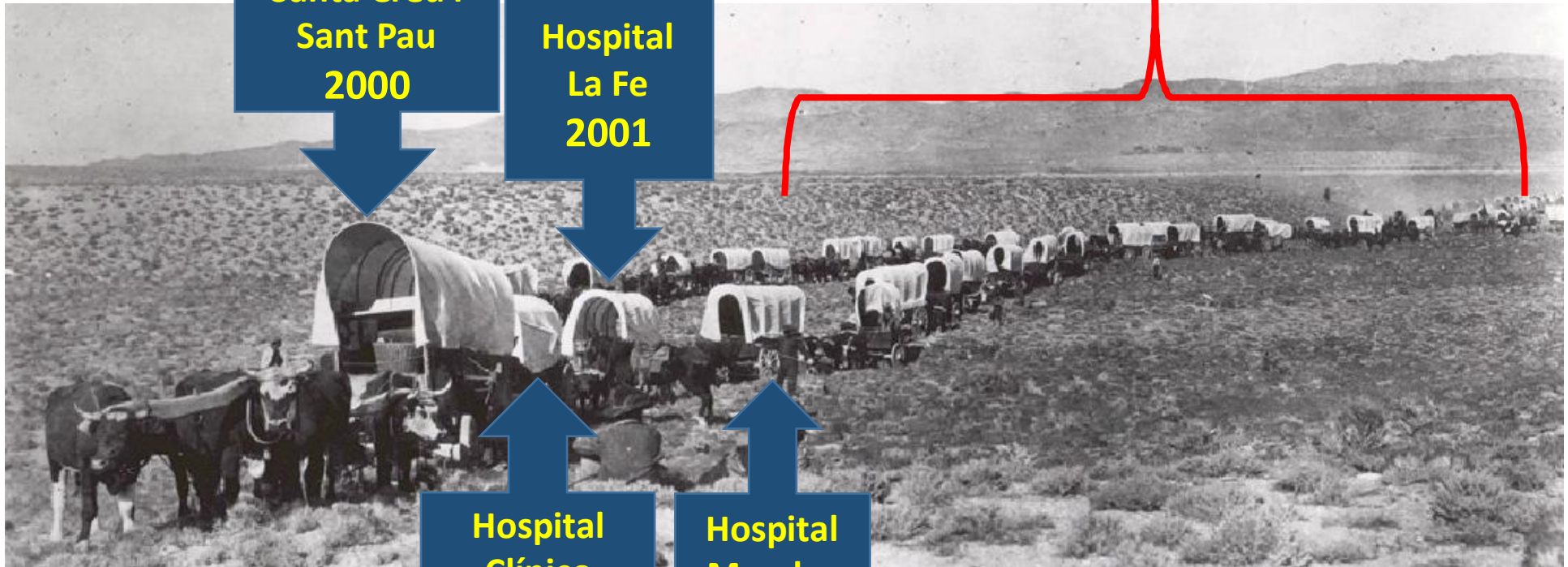
Resto de Europa

**Hospital de la Santa Creu i Sant Pau
2000**

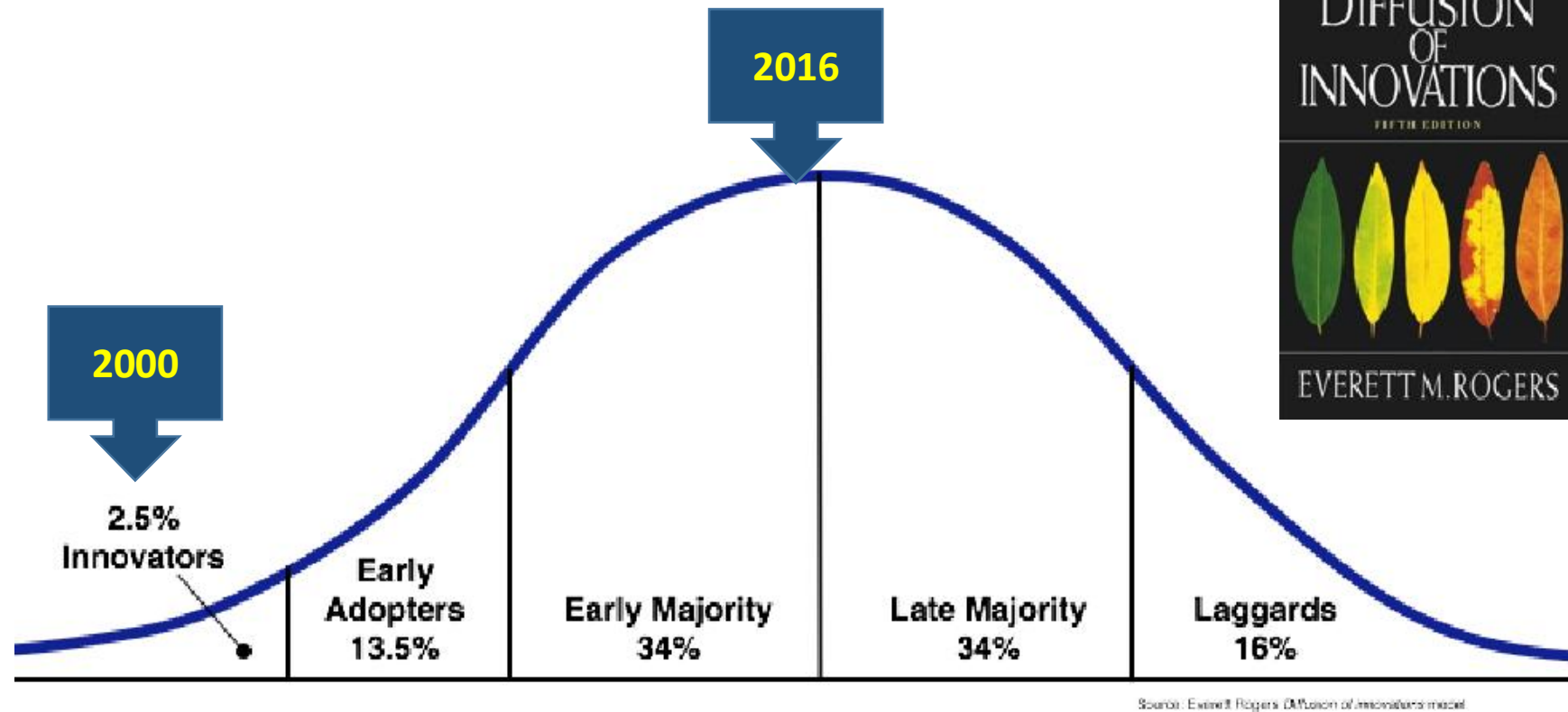
**Hospital La Fe
2001**

**Hospital Clínico Salamanca
2000**

**Hospital Morales Meseguer
2002**



Modelo <Difusión de innovaciones> – adaptado a la incorporación de JACIE

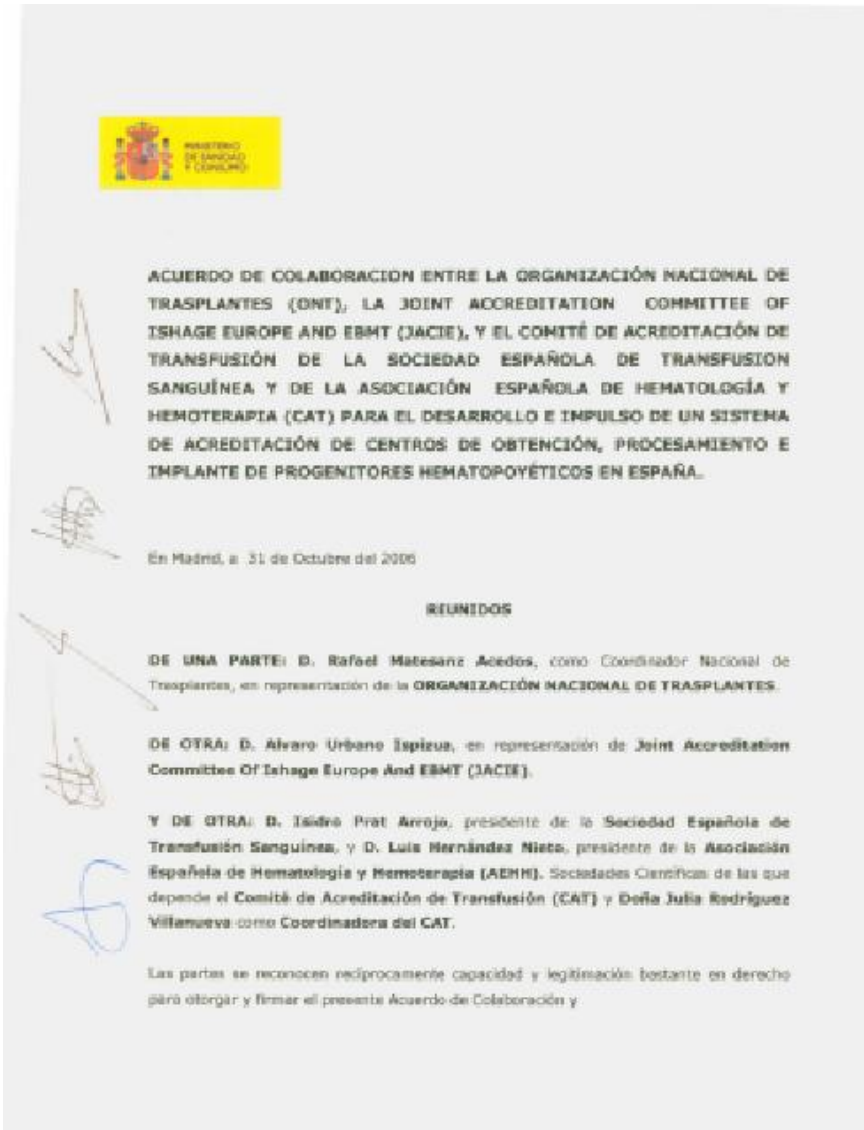


“Diffusion of Innovation” model, ([Everett Rogers, 1962](#))

Factores contributivos

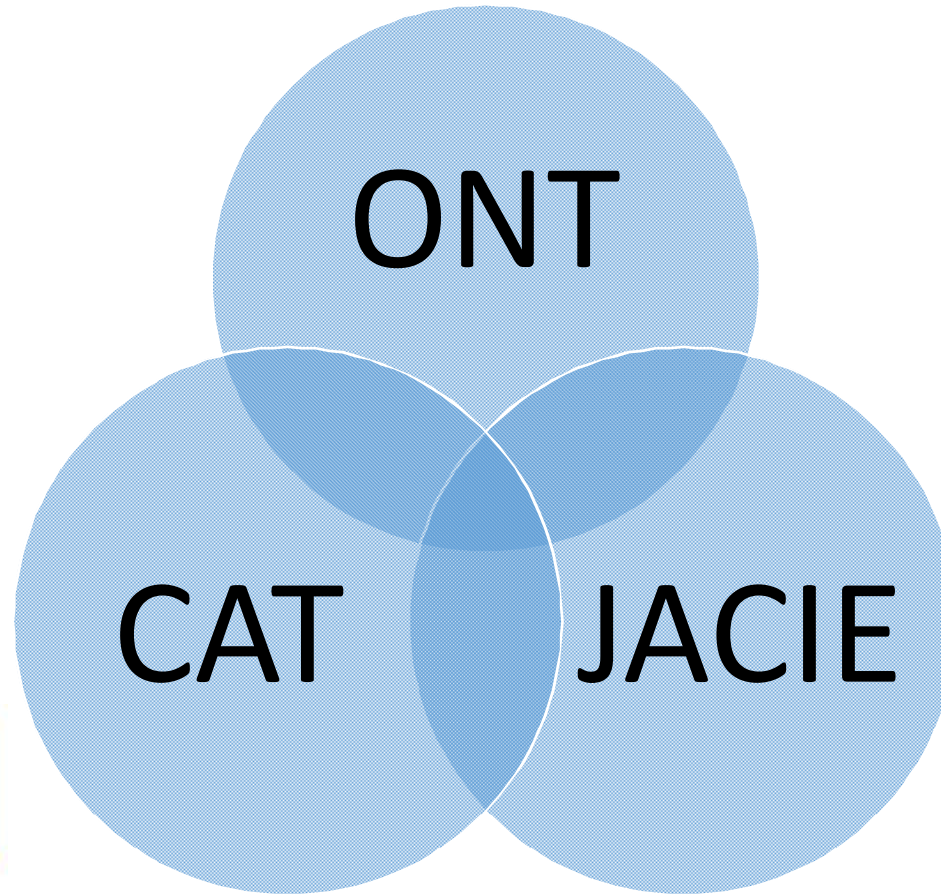
- La Oficina de JACIE está en Barcelona
 - Equipo local, castellanohablante
- Tres Secretarios españoles del EBMT – Alvaro Urbano, Anna Sureda, Rafael Duarte
- Comité de Acreditación en Transfusión (CAT) – cultura de calidad en los bancos de sangre
- Actitud positiva de la ONT
- Coincidió con los primeros directivos europeos de tejidos y células (EC 2004/23/EC)

Comité Conjunto de Acreditación (CCA)



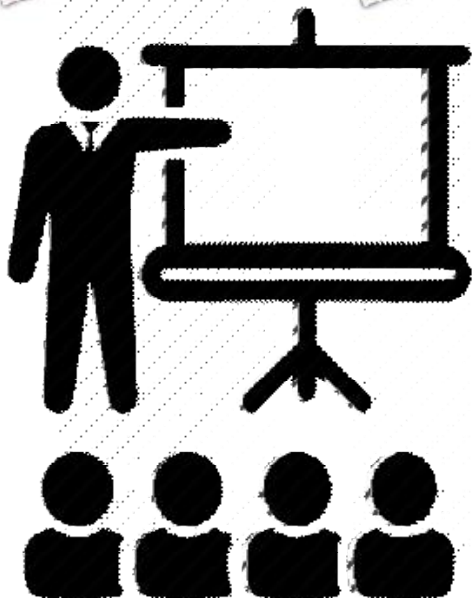
- 31 Octubre 2006

CCA

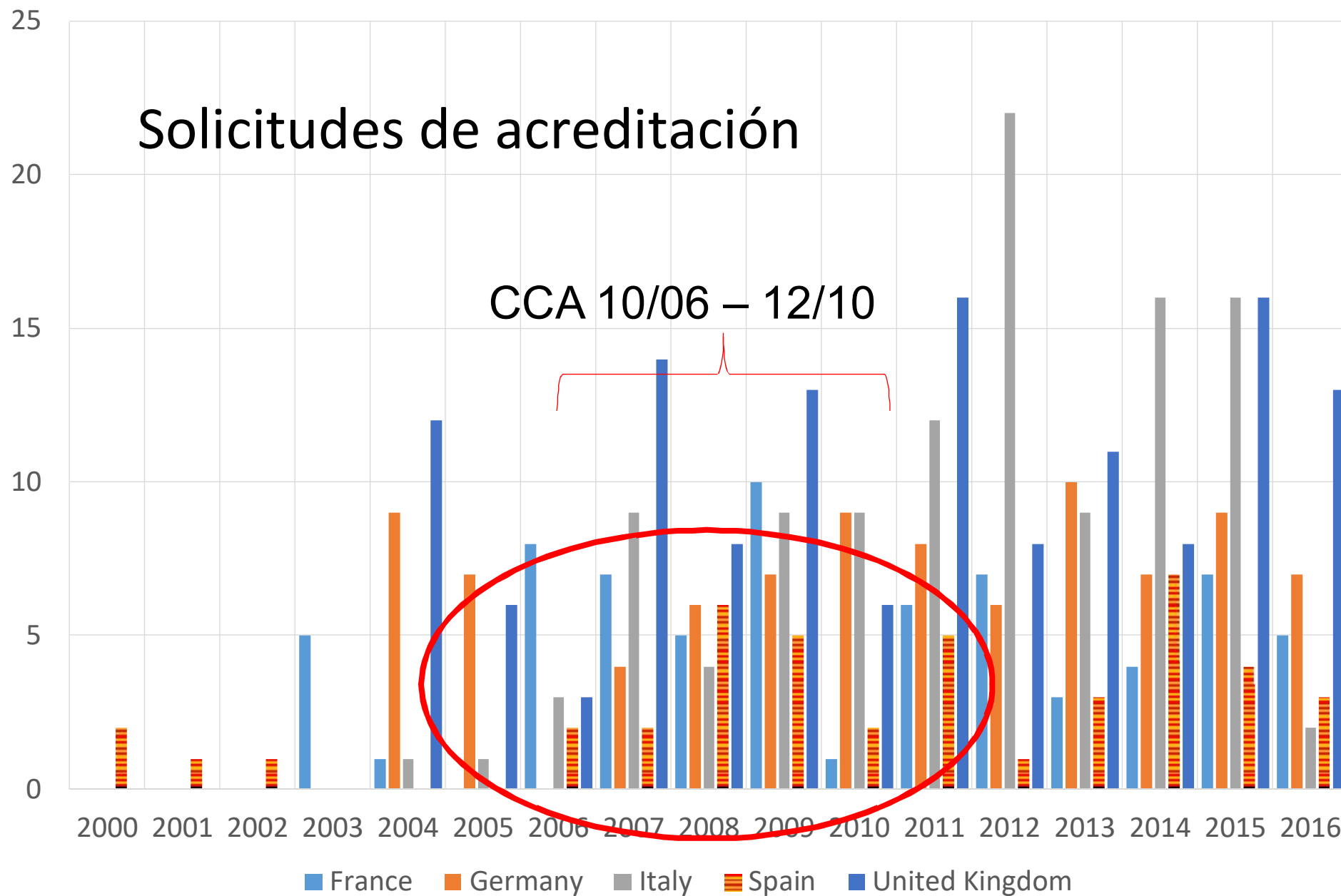


CCA – aportaciones

EXPERIENCIA



Solicitudes de acreditación



Impacto de calidad

Research in Society of Clinical Oncology

Introduction of a Quality Management System and Outcome After Hematopoietic Stem-Cell Transplantation

Alois Gratwohl, Ronald Brand, Dierger Niederwieser, Helen Baldomero, Christian Chabannon, Jan Cornelissen, Ilona de Witte, Per Ljungman, Fiona McDonald, Eoin McGrath, Jakob Passweg, Christina Peters, Vanderson Rocha, Ineke Slaper-Cortenbach, Anna Sureda, Andre Tichelli and Jane Apperley

This Article

Published online first April 11, 2013
 DOI: 10.1200/JCO.2012.40.4121

Abstract PDF

Full-text Article
 View Publishing Info

Classifications
 Cancers: Hematologic Neoplasms

Services

EUROPEAN HEMATOLOGY ASSOCIATION

haematologica
 Journal of the European Hematology Association

Use of the quality management system "JACIE" and outcome after hematopoietic stem cell transplantation

by Alois Gratwohl, Ronald Brand, Eoin McGrath, Anja van Biezen, Anna Sureda, Per Ljungman, Helen Baldomero, Christian Chabannon, and Jane Apperley

Haematologica 2013 [Epub ahead of print]

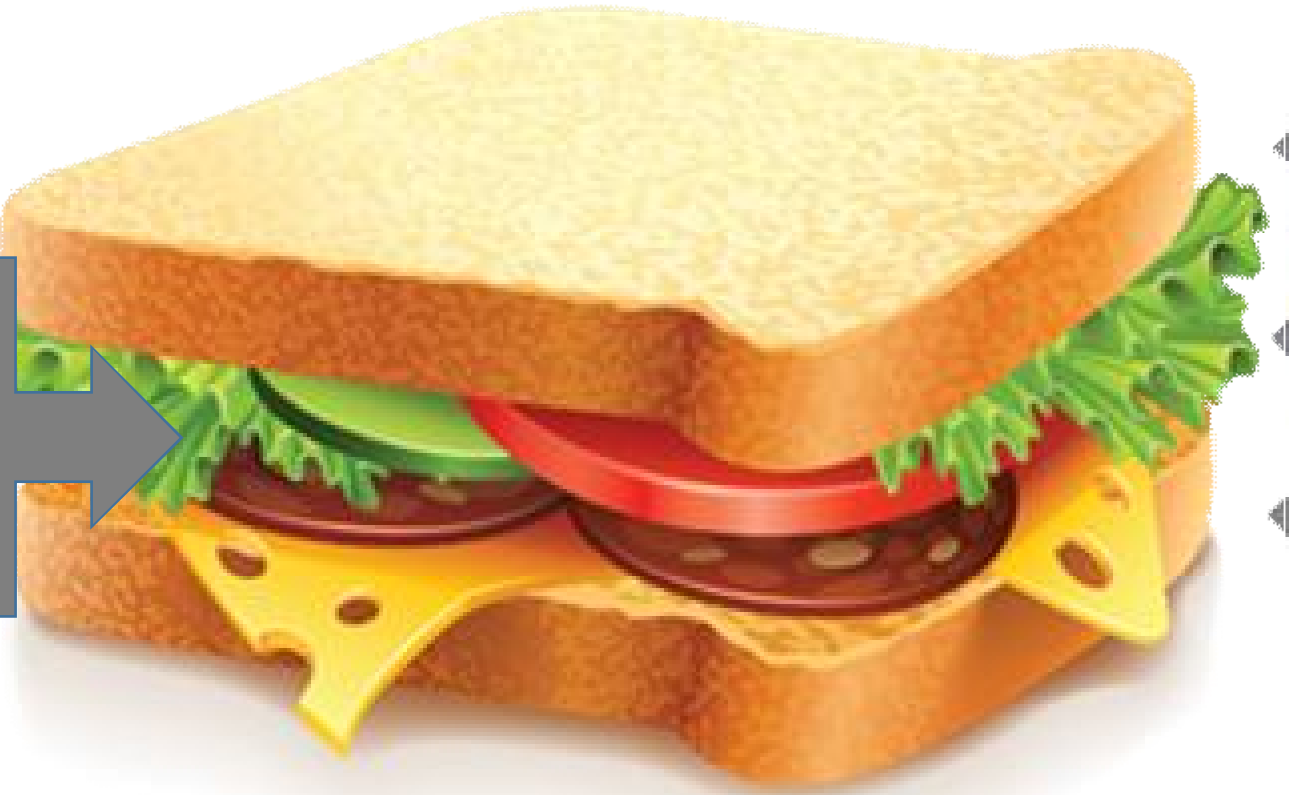
Citation: Gratwohl A, Brand R, McGrath E, van Biezen A, Sureda A, Ljungman P, Baldomero H, Chabannon C, and Apperley J. Use of the quality management system "JACIE" and outcome after hematopoietic stem cell transplantation. *Haematologica*. 2014; 99:xxx
 doi:10.3324/haematol.2013.096464

Impacto clínico

calendar time. Overall mortality of the entire cohort of 107,904 patients with a transplant (41,623 allogeneic, 39%; 66,281 autologous, 61%) between 1999 and 2006 decreased over the 14 years observation period by a factor of 0.63 per 10 years (HR: 0.63; 0.58-0.69). This improvement was significantly faster with approx. 5.3% per year for the 49,459 patients transplanted in "JACIE" accredited centers, defined as programs having achieved accreditation the latest by November 2012, than the approx. 3.5% per year for the 58,445 patients in non accredited centers (HR: 0.83; 0.71-0.97). As a result, relapse free (HR 0.85; 0.75-0.95) and overall survival (HR 0.86; 0.76-0.98) were significantly higher at 72 months for those patients transplanted in the 162 "JACIE" accredited centers. No significant effects were observed after autologous transplants (HR 1.06; 0.99-1.13). Hence, working towards implementation of a quality management system triggers a dynamic process associated with a steeper reduction in mortality over the years and a significantly improved survival after allogeneic stem cell transplantation. Our data support the use of a quality management system for complex medical procedures.

'Good News Sandwich'

Not-so-good news



Modelo de administración



Trabajo en red

- También ha sido difícil generar colaboración extensiva entre los centros Ej. foros, intercambio de experiencias, soluciones
 - Sí hubo interacciones locals/regionales



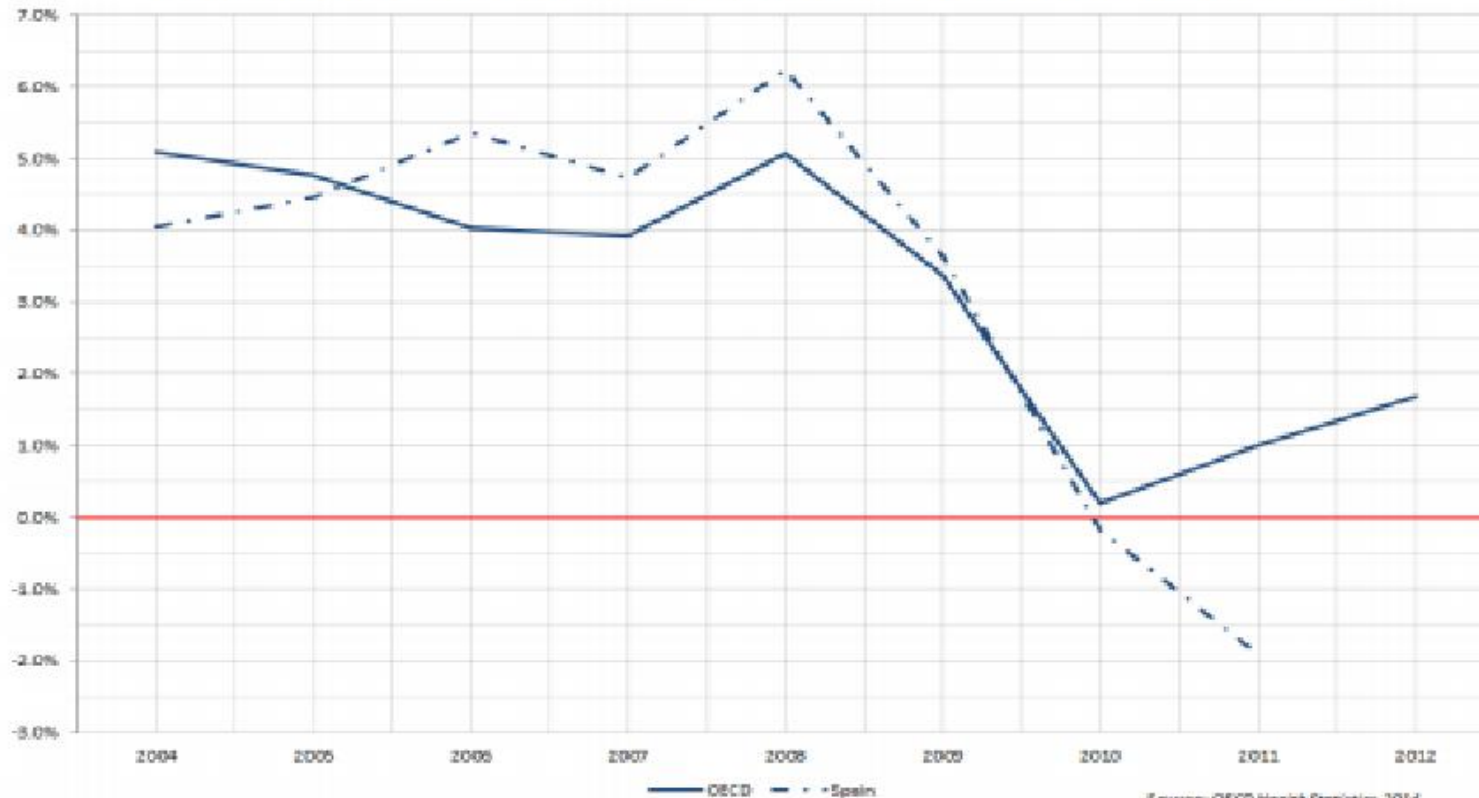
Health care in Spain

Is Spain on the verge of a public health-care crisis?

Dec 16th 2013, 17:49 BY S.N.



Health expenditure growth rates (in real terms) since 2004, Spain and OECD average



Source: OECD Health Statistics 2014

<http://www.oecd.org/els/health-systems/Briefing-Note-SPAIN-2014.pdf>



Cultura de calidad



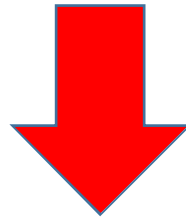
Patient safety, satisfaction, and quality of hospital care: cross sectional surveys of nurses and patients in 12 countries in Europe and the United States
BMJ 2012; 344 doi: <http://dx.doi.org/10.1136/bmj.e1717> (Published 20 March 2012) Cite this as: *BMJ* 2012;344:e1717 <http://www.bmj.com/content/344/bmj.e1717>

Differences in quality of care assessments among countries

We noted differences in quality of care assessments among countries. Nurses' ratings of quality and job satisfaction were worst in Greece, whose health system has had severe economic difficulties and where there have been widespread protests about the government's austerity measures. Spain, which ranked third worst on quality, has also had austerity protests. Germany ranked second worst, and although it has not faced protests, its nursing workload is thought to have increased after the introduction of case based payment. By contrast, nurses in Ireland and Finland reported high levels of quality, although both countries have also had considerable economic downturns, whereas the good performance of Norway's well resourced health system was expected.

Prioridades

JACIE



Quality Manager

- El rôl existe pero no alcanza el mismo nivel que en otros países Ej. Reino Unido
- Suele compartir actividades asistenciales con las de calidad
 - Prioridades



Take-up among transplant centres*

- Percentage of transplanting centres reporting to the 2014 EBMT Activity Survey* that have applied, been inspected or been accredited since 2000

Transplants	Global	Spain	UK	Italy	Germany	France
All types	42%	29%	88%	65%	47%	43%
Auto	21%	0%	88%	24%	9%	14%
Allo	59%	59%	100%	85%	74%	71%

OPEN

Bone Marrow Transplantation (2016), 1-7
 © 2016 Macmillan Publishers Limited. All rights reserved. 0268-3390/16
www.nature.com/bmt



ORIGINAL ARTICLE

Hematopoietic stem cell transplantation in Europe 2014: more than 40000 transplants annually

JR Passweg¹, H Baldomero¹, P Bader², C Bonini³, S Cesaro⁴, P Dreger⁵, RF Duarte⁶, C Dufour⁷, J Kuball⁸, D Farge-Bancel⁹, A Gennery¹⁰, N Kröger¹¹, F Lanza¹², A Nagler¹³, A Sureda⁹ and M Mohty¹⁴ for the European Society for Blood and Marrow Transplantation (EBMT)

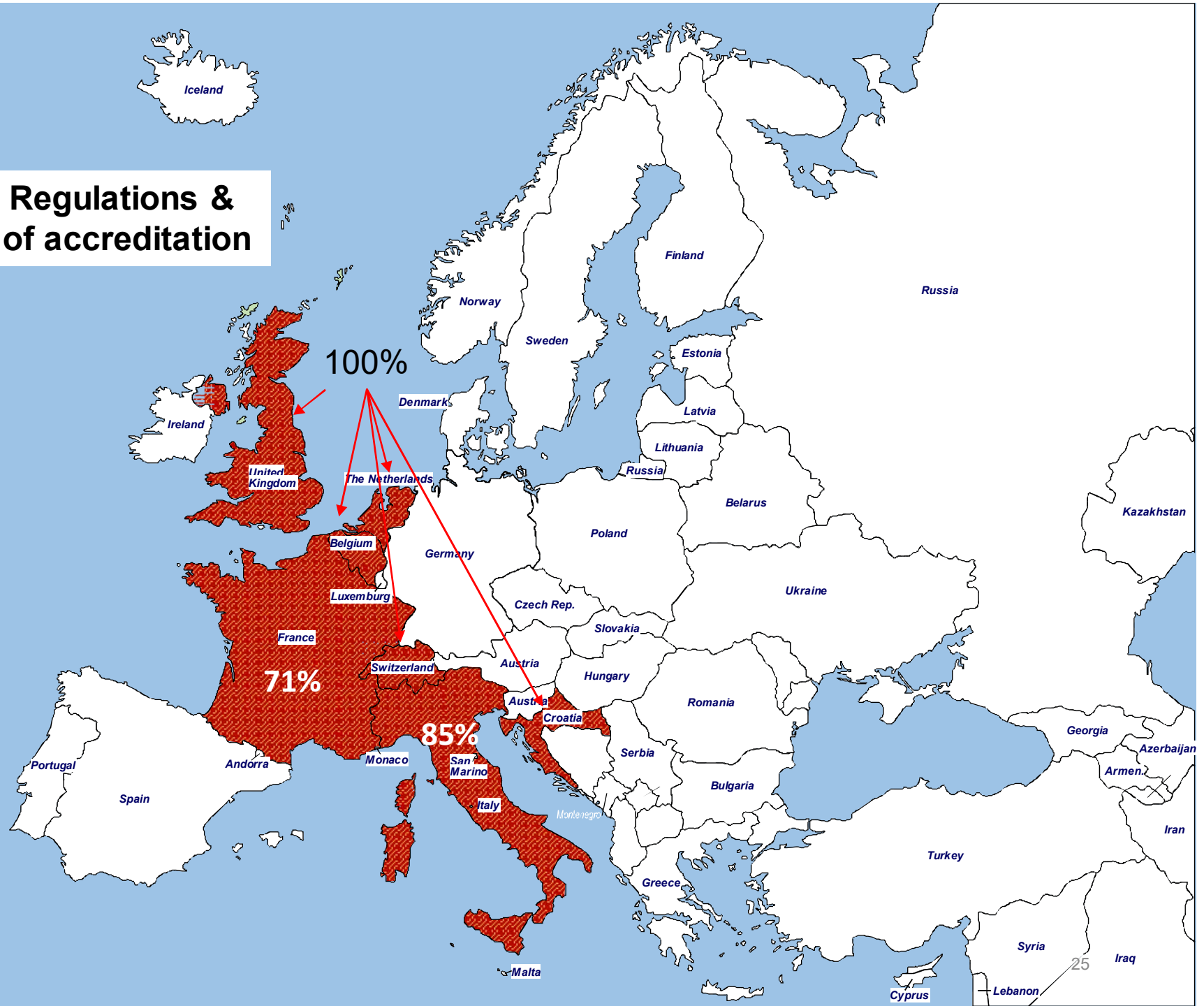
*data May 2016



JACIE & Regulations



JACIE & Regulations & Take-up of accreditation



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Interim standards
6th edition

▼ **Applicants**

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Regulations

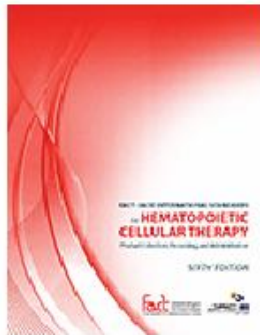
- **France** Engagement with JACIE a requirement for allogeneic transplant centres according to Arrêté du 3 avril 2009 relatif au contenu du document d'évaluation des activités de greffes d'organes et de greffes de cellules hématopoïétiques
- **Belgium** JACIE accreditation will be a legal requirement for transplantation centers (doing autologous and/or allogeneic transplantations) in Belgium for reimbursement by the social security according to *C-2012/22474 Arrêté royal modifiant l'article 20, § 1er, a), de l'annexe à l'arrêté royal du 14 septembre 1984* published 21-12-2012.
- **NEW Croatia** Ordinance *Pravilnik o uvjetima u pogledu prostora, siročnih radnika, medicinsko-tehničke opreme i sustava kvalitete za obavljanje djelatnosti prikupljanja, uzimanja, testiranja, obrade, očuvanja, pohrane i raspodjele ljudskih tkiva i stanicahaematopoietic*. Art 35 (2) "progenitor cells bank must be accredited according to the JACIE standards".
- **Switzerland** Accreditation required to receive reimbursement from Social Insurance for treatments. *Ordonnance du DFI sur les prestations dans l'assurance obligatoire des soins en cas de maladie (Ordonnance sur les prestations de l'assurance des soins, OPAS)*
- **Italy** Decreto Legislativo 25 gennaio 2010, n.16 implementing the European Directives on Tissues and Cells cites a 2003 agreement recognising JACIE
- **The Netherlands** Accreditation required to receive authorisation to transplant from Ministry of Health

Guidelines

- **Belgium** Reference to JACIE standards in specific standards of the Superior Health Council "*Standards de qualité pour les tissus et cellules reproducteurs / Kwaliteitsnormen voor reproductieve weefsels en cellen*" 5 August 2009.
- **European Directorate for the Quality of Medicines & HealthCare**
 - Guide to the quality & safety of tissues and cells for human application, 1st edition (2013)
 - Guide to the Safety and quality assurance for the transplantation of organs, tissues and cells, 4th edition (2010)
- **EU-BIS - European Blood Inspection System** - Common European Standards and Criteria for the Inspection of Blood Establishments. Audit / Inspection – Training Guide. Ed. 1.0.
- **Germany** Zentrales Knochenmarkspender-Register Deutschland (ZKRD) German Standards for Unrelated Blood Stem Cell Donations Version 8 2012-06-20
- **Italy** Piano Oncologico Nazionale 2010-2012 cites JACIE accreditation
- **Philippines** The Rules and Regulations Governing the Accreditation of Health Facilities Engaging in Human Stem Cell and Cell-Based or Cellular Therapies in the Philippines cite the FACT-JACIE Standards.
- **United Kingdom**
 - JACIE cited in National Institute for Health and Clinical Excellence (NICE) guidelines
 - Manual for Cancer Services Haemato-oncology Cancer Measures Version 1.0 (2013)
 - Improving Outcomes in Children and Young People with Cancer (2005)
 - Improving Outcomes in Haematological Cancers (2003)
 - The Future of Unrelated Donor Stem Cell Transplantation in the UK. A Report from the UK Stem Cell Strategic Forum (July 2010). NII3DT
 - JACIE cited in Specialised Services National Definitions Set (3rd edition) SSNSD Definition No.2, Specialised Services for Blood and Marrow Transplantation (all ages)

Idioma

- Versión en español de los estándares 6ª edición – “ESTÁNDARES INTERNACIONALES PARA LA RECOLECCIÓN, PROCESAMIENTO Y ADMINISTRACIÓN DE PRODUCTOS HEMATOPOYETICOS DE TERAPIA CELULAR”
- Distribuida por FACT (EE.UU)



[FACT-JACIE Sexta Edición Estándares Internacionales Para la Recolección, Procesamiento y Administración de Productos Hematopoyeticos de Terapia Celular \[Descargar Gratis\] \(#645\)](#)

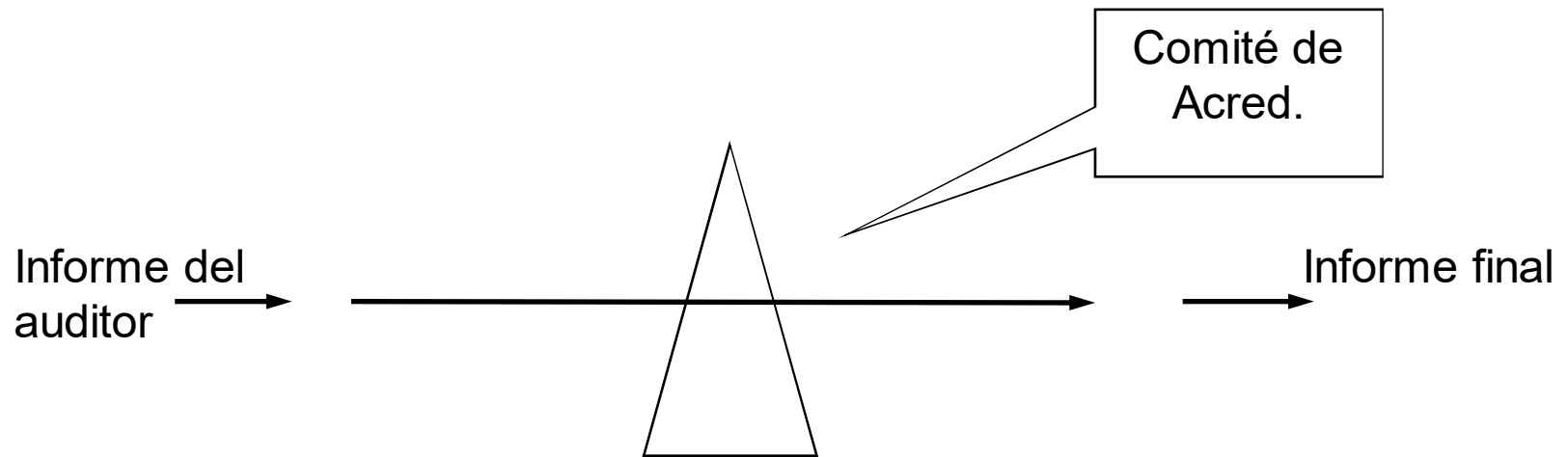
Estos Estándares están diseñados para proveer directrices mínimas para programas, instituciones e individuos que llevan a cabo trasplante de células y terapia o que proveen servicios de soporte para dichos procedimientos.

Accredited Organization, Guest, Inspector, Inspector Trainee, NonMember - \$0.00

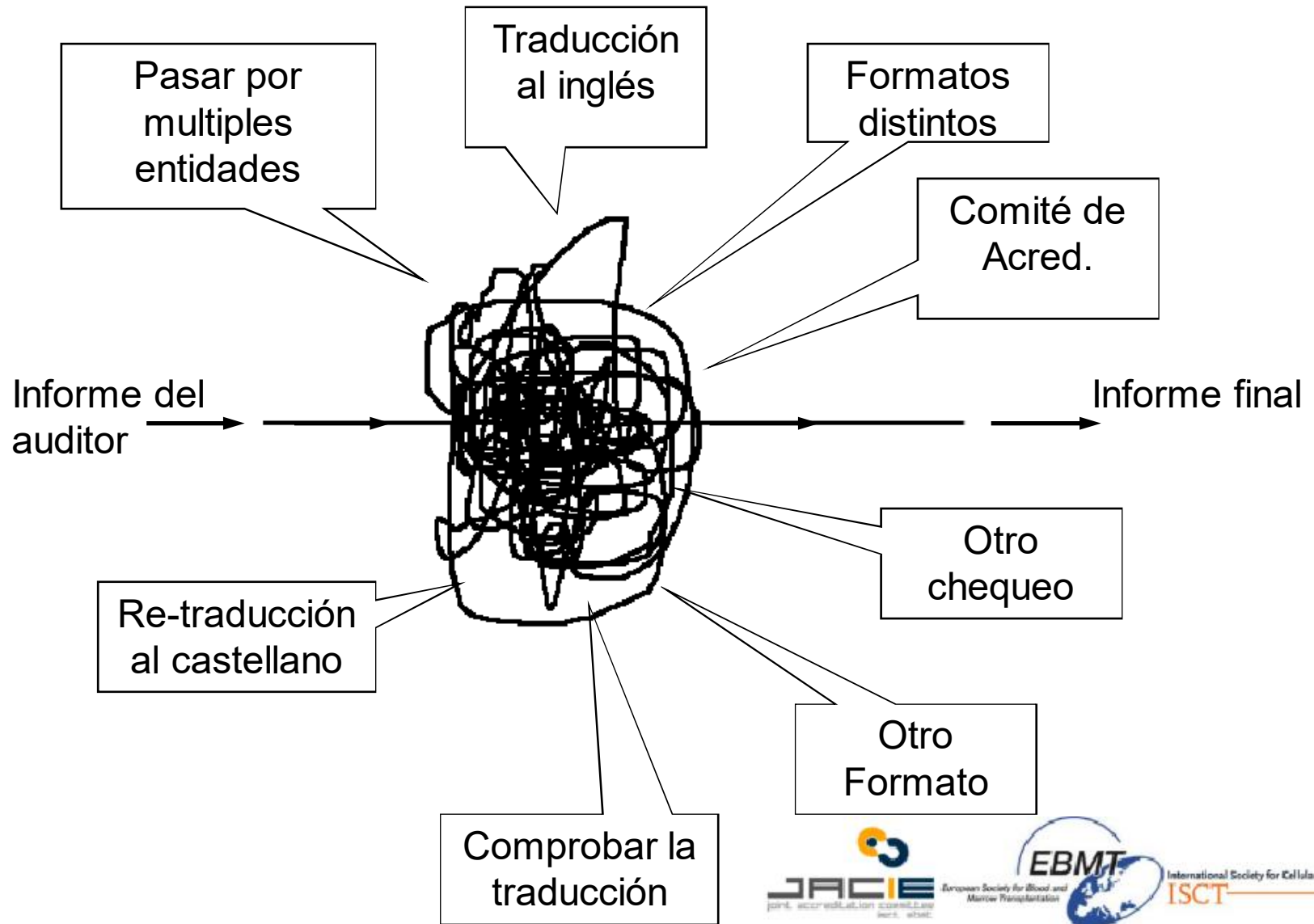
[Add to Cart](#)

<http://www.factweb.org/forms/store/CommercePlusFormPublic/search?action=Publications>

Proceso acreditación – LO QUE QUEREMOS



Proceso acreditación – LO QUE **NO** QUEREMOS



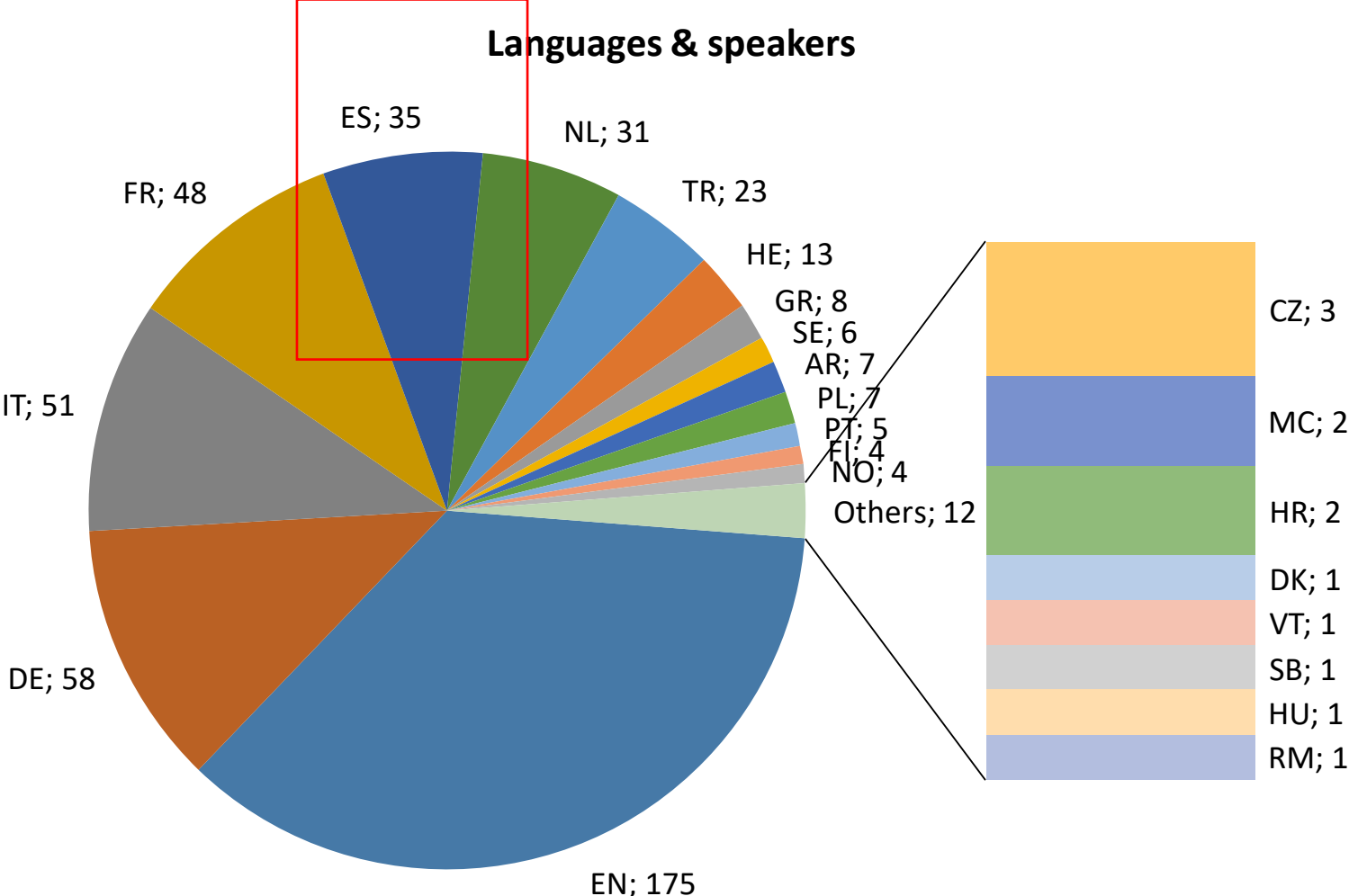
Inspectores

- Elemento fundamental del proceso
- Trabajo exigente pero enriquecedor
- Criterio
 - 5 años de experiencia en su campo (clínico, obtención, procesamiento)
 - Asistir al curso de formación
 - Aprobar examen
 - Participar como observador

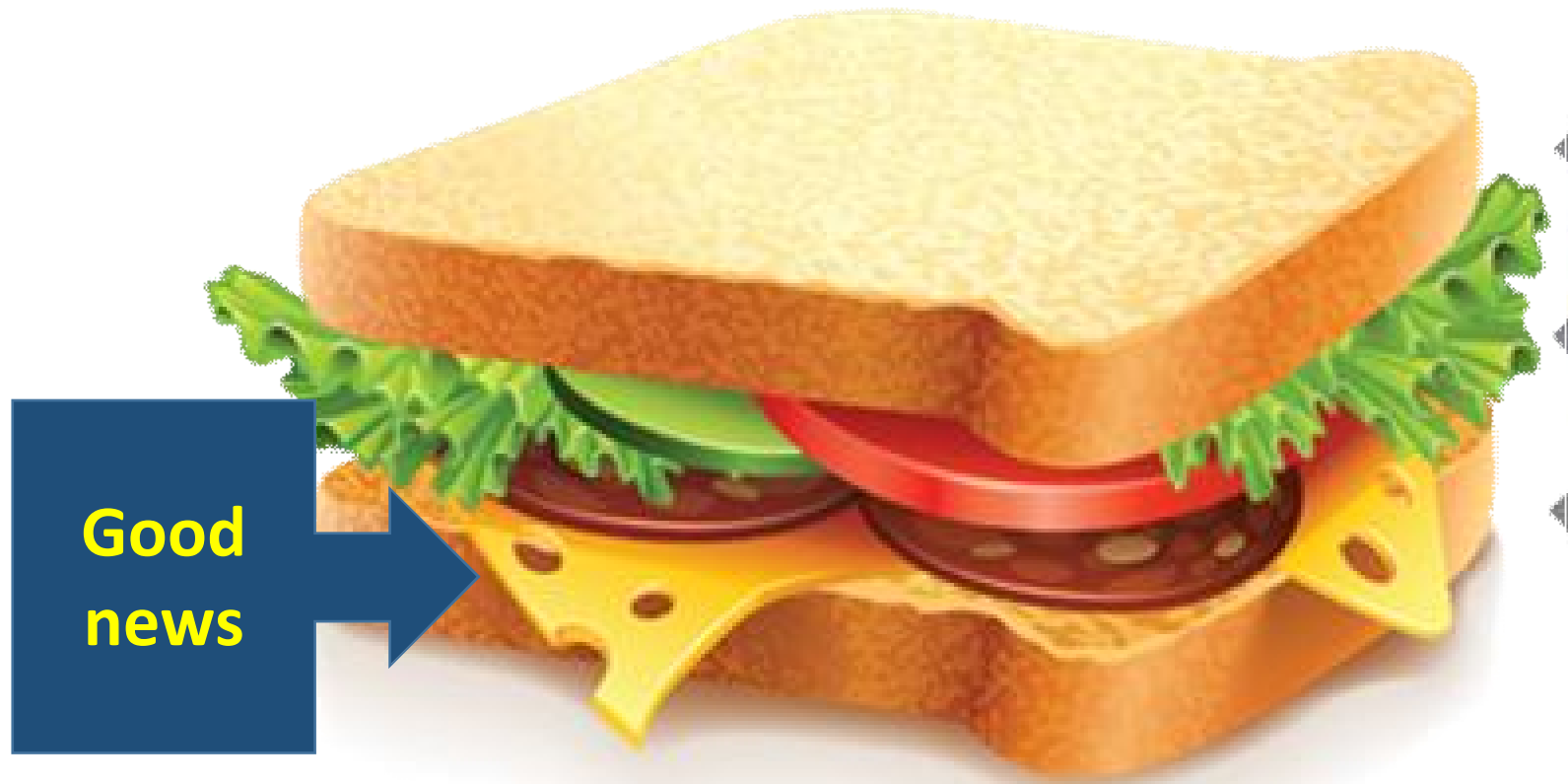
Inspectores

"No hay mejor manera
para aprender"

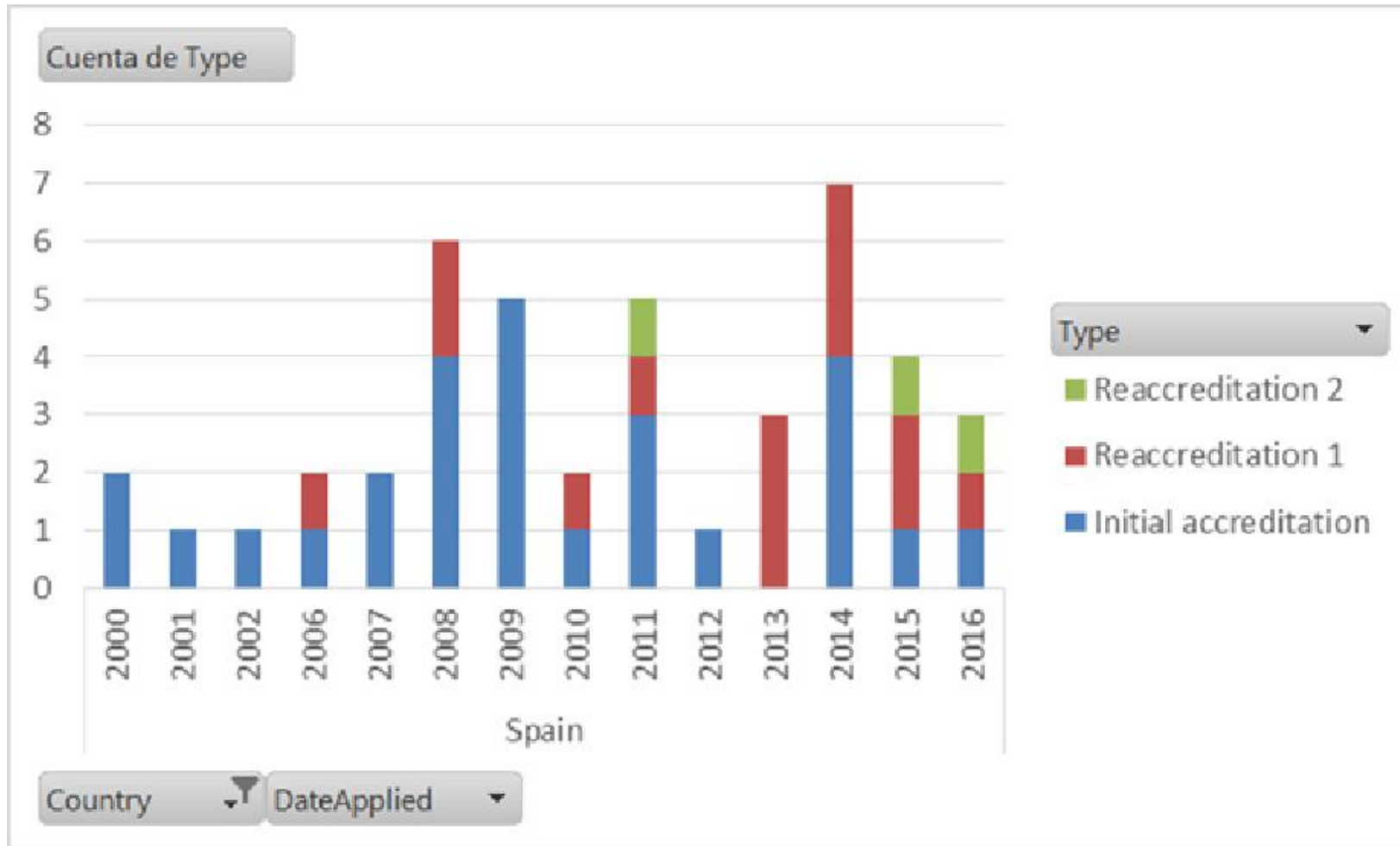
Languages & inspectors



'Good News Sandwich'



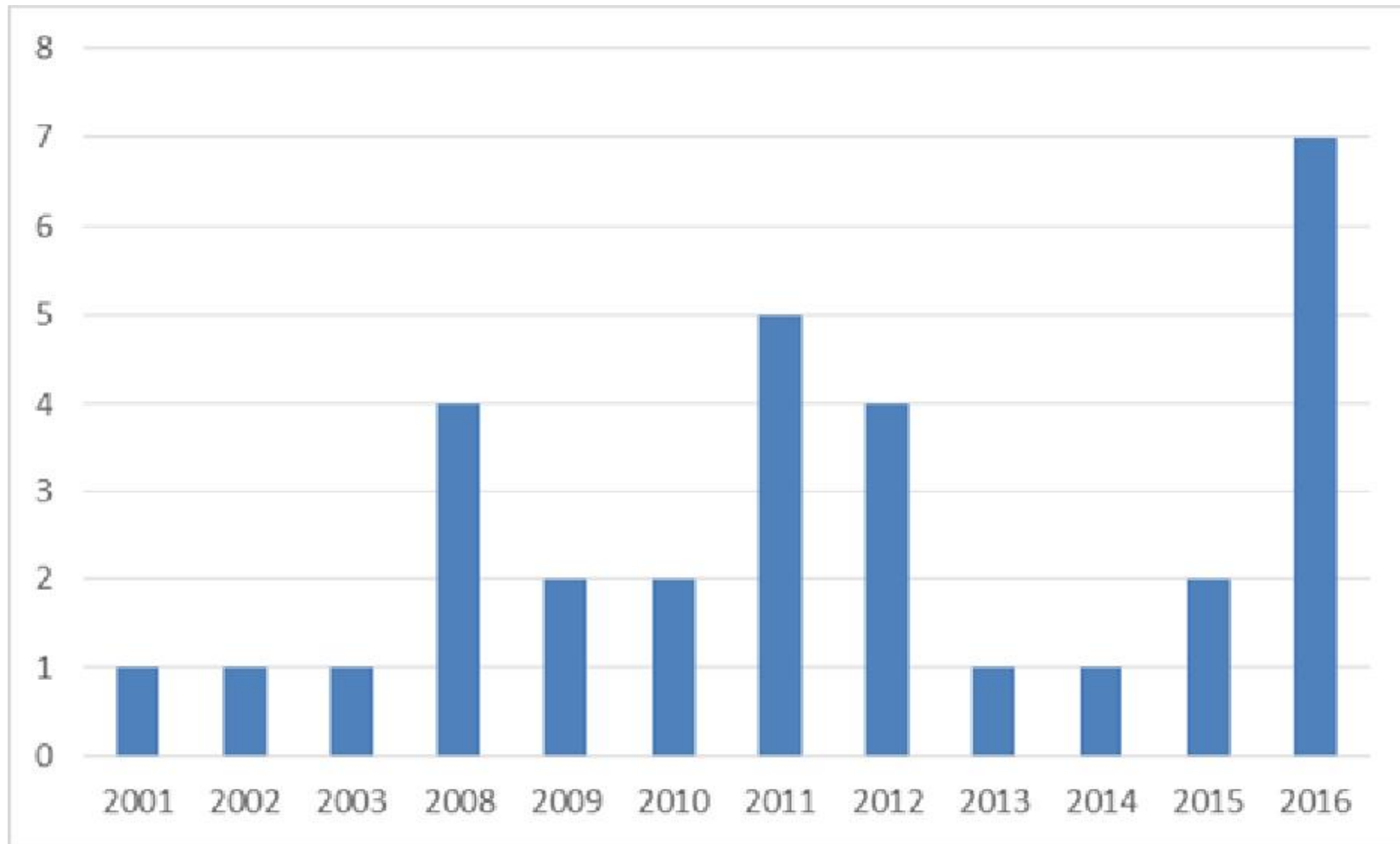
Solicitudes - España



Inspecciones - España



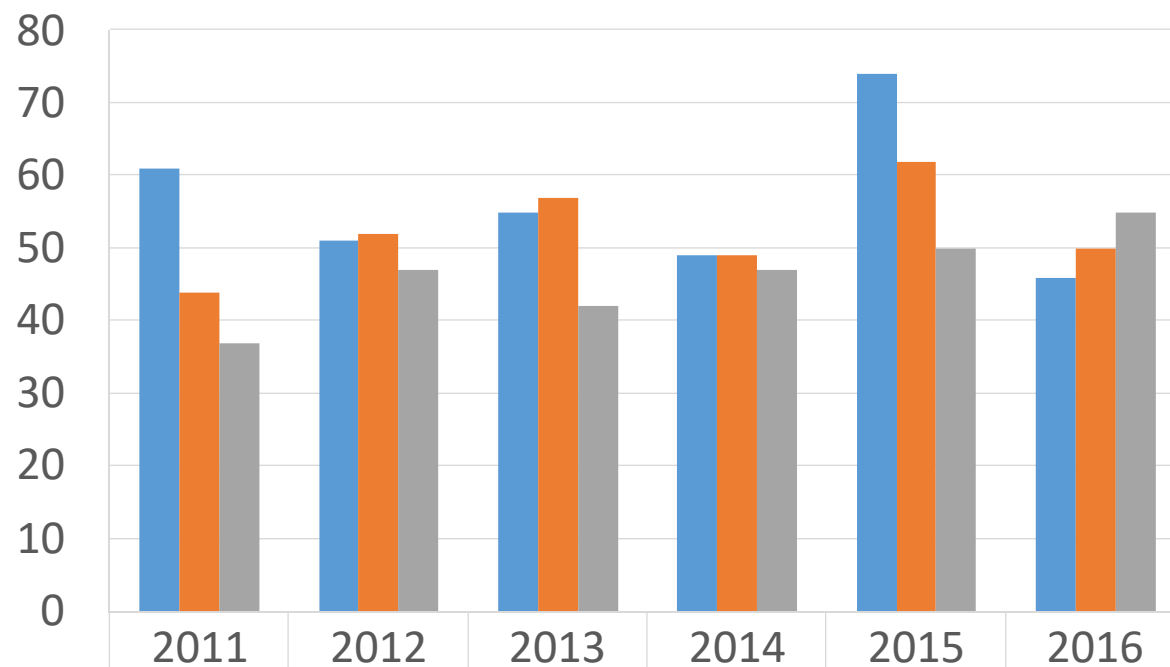
Accreditaciones - España



Acreditaciones actuales - España- año de caducidad

Year	2017	2018	2019	2020	Total
Spain	1	1	2	6	10

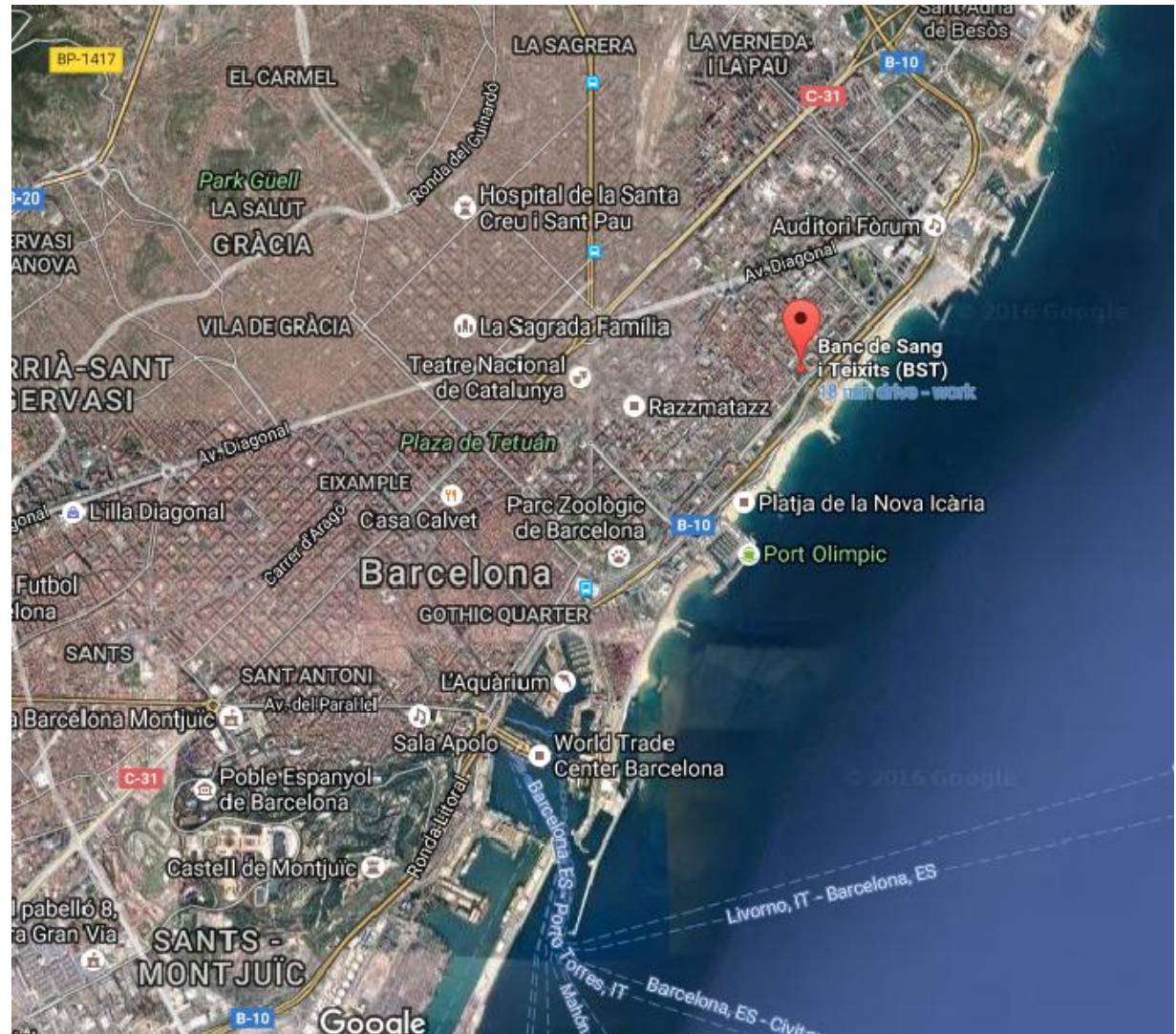
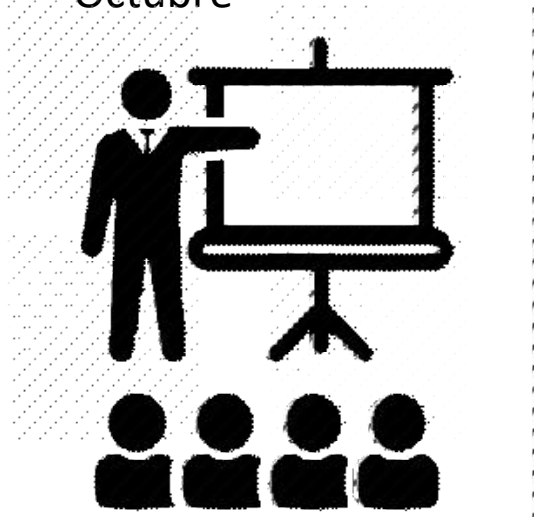
Global activity



■ Applications	61	51	55	49	74	46
■ Inspections-completed	44	52	57	49	62	50
■ Accreditations	37	47	42	47	50	55

Secretariado JACIE

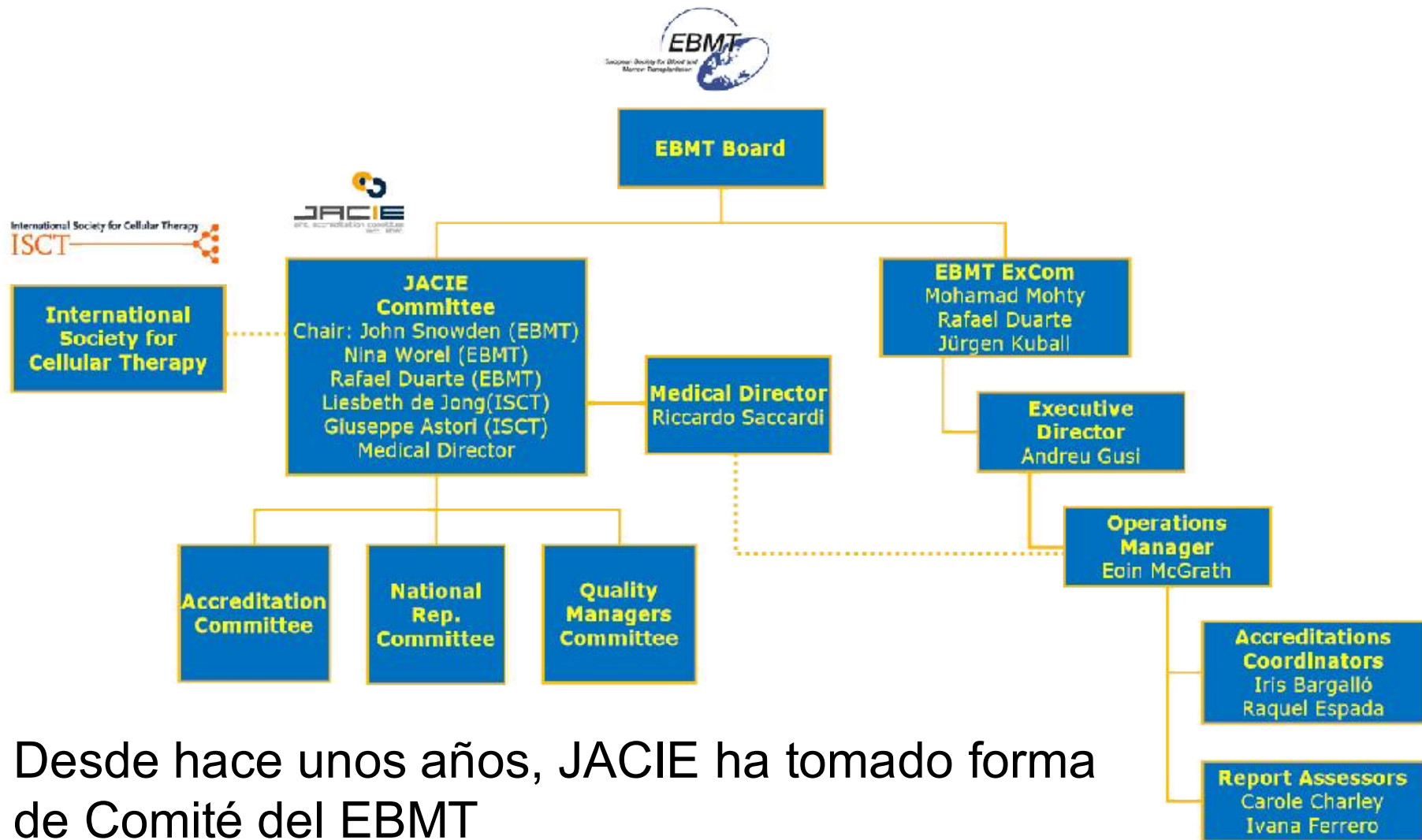
- Barcelona
 - Banc de Sang i Teixits
- 3 natives + 1 irlandés castellanoparlante
- Organizar cursos cada año
 - 2017 – planificamos dos en Barcelona - Mayo y Octubre



Proyectos

- **FACT-JACIE Estándares**
 - 6ª edición – consulta abierta sobre requisitos nuevos para la administración de células inmunoreceptores
 - 7ª edición
 - Fase sub-comités
 - Consulta pública Apr-Jun 2017
- **Proceso escalado para Sud América en colaboración con FACT**
 - Proceso ampliado a 3 pasos
- **Educación / motivación / retención de auditores**
 - Coordinadora dedicada a recursos humanos
- **Evaluando alternativas tipo ‘apps’ para sustituir el Checklist Excel actual**

Structure & Reporting lines



Desde hace unos años, JACIE ha tomado forma de Comité del EBMT

Más cerca al Board que antes = más APOYO

JACIE Committee



Chair
John Snowden
Sheffield, UK



EBMT Representative
Nina Worel
Vienna, Austria



EBMT Representative
Rafael Duarte
EBMT Secretary
Barcelona, Spain



ISCT Representative
Giuseppe Astori
Vicenza, Italy



ISCT Representative
Liesbeth de Jong
Sevilla, Spain



JACIE Medical Director
Riccardo Saccardi
Florence, Italy

2016 - Nueva colaboración JACIE-CAT-ONT

- Incentivar
- Facilitar
- Optimizar

- Aprender del pasado





PI. 5
EBMT/JACIE

PI. 2
Coordinadora
CAT

Redes sociales



<https://www.linkedin.com/groups/5027189>



@JACIE_EBMT



Gracias a.....

- Enric Carreras
 - Ángel Cedillo
 - Felipe de Arriba
 - Rafael Duarte
 - Christelle Ferrá
 - José M^a Moraleda
 - Carlos Solano
 - Alvaro Urbano
 - Marta Torrabadella
 - ...
-
- Sobre todo, a los Inspectores y los Centros

Gracias