

# Standards and Accreditation - JACIE



The Joint Accreditation Committee ISCT-Europe & EBMT (JACIE) was established in 1998. It promotes high-quality patient care and laboratory performance in the collection, processing and administration of cellular therapy through a profession-led, voluntary accreditation scheme.

JACIE works continuously with international partner organisations to develop and maintain standards for the provision of quality medical and laboratory practice in HSCT, performs on-site inspections, and accredits those programmes that demonstrate compliance with these standards. JACIE also provides training for inspectors and centres on the accreditation process.

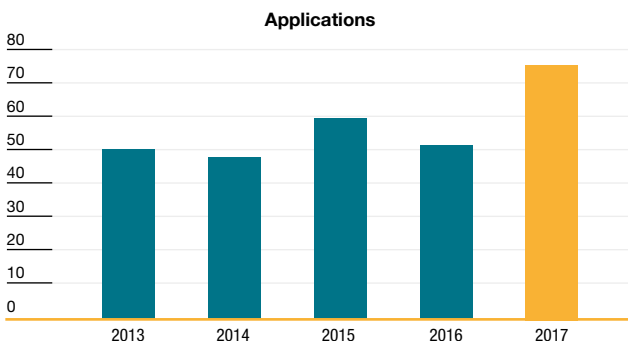
Since 2000, **393 transplant programmes and facilities in 26 countries** in Europe and beyond have applied to JACIE and **544 inspections** (first-time and reaccreditation) have been performed. Over 300 applicants have achieved accreditation at least once with practically all centres repeating the process after completing the first accreditation cycle. There are over 260 registered inspectors, all volunteers drawn from the cellular therapy field.

2017 saw the highest number of applications ever and second highest number of accreditations.

## Applications 2017

**75 applications** (15 first-time and 60 reaccreditation) received (see figure 1).

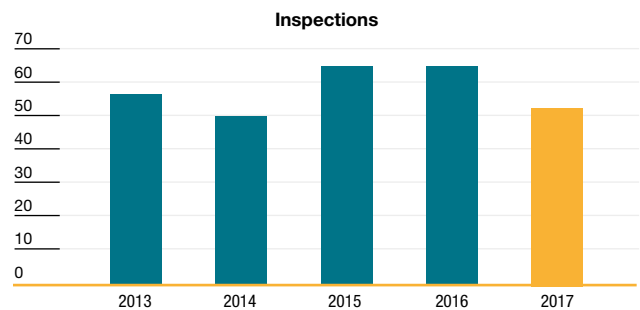
Figure 1. Number of applications received for the past five years



## Inspections 2017

**53 inspections** (10 first-time and 43 reaccreditation) (see figure 2).

Figure 2. Number of inspections performed for the past five years



## Accreditations 2017

**51 accreditations** (13 first-time and 38 reaccreditation) awarded (See figure 3).

Figure 3. Number of accreditations awarded for the past five years

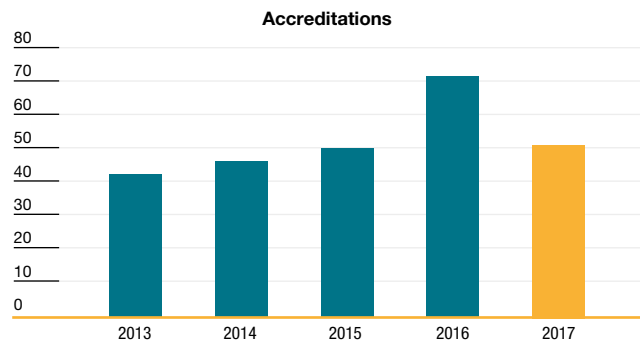
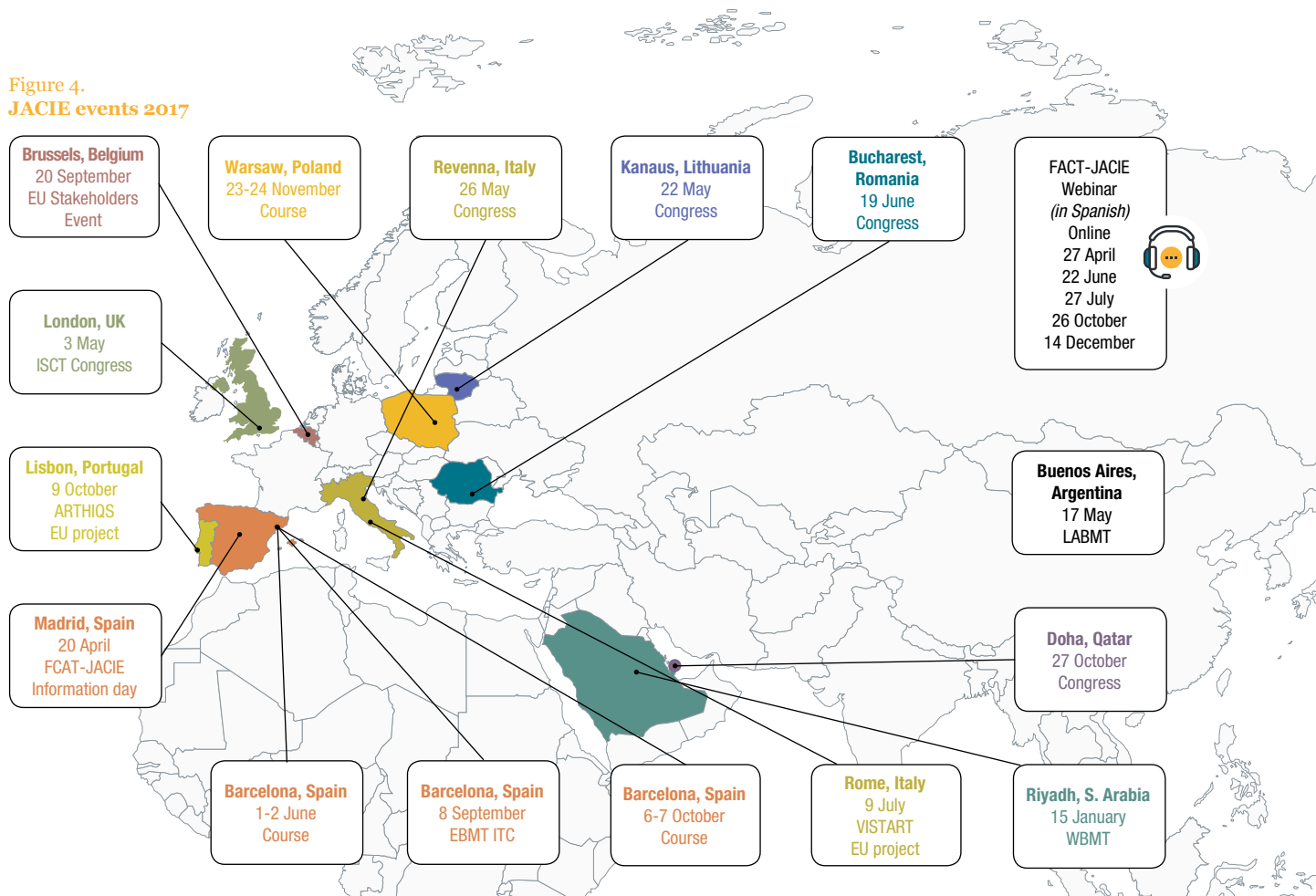


Figure 4.  
JACIE events 2017



## 7<sup>th</sup> Edition of FACT-JACIE Standards

Work on preparing the 7<sup>th</sup> edition of the FACT-JACIE Standards started in June 2017 with a meeting of the FACT and JACIE teams in Barcelona. Through the second half of 2017, the standards sub-committees worked on their respective sections of the Standards. One significant development for this edition is that a dedicated Quality Management sub-committee has been incorporated into the process which will bring more focus to these standards and bring to bear the experience of quality managers.

The 7<sup>th</sup> edition will be published on 1 March 2018.



Figure 5.  
Participants at the JACIE Training Courses 2017 in Barcelona and Warsaw

## Educational events

Three well-attended JACIE training courses were held: two in Barcelona, (**Spain**) and another in Warsaw (**Poland**) with 63 participants in total. In addition, a joint event was held in Buenos Aires (**Argentina**) in May at the LABMT congress with 50 attendees. Furthermore, a series of FACT-JACIE Spanish-language webinars were run for South American centres. JACIE was also represented in several other events and projects throughout the year (See figure 4 above).





## Advocacy and institutional relations

In recent years EBMT has established good relations with DG SANTÉ (Public Health Commission) and the European Medicines Agency (EMA). JACIE coordinates EBMT's interactions with European bodies.

### DG SANTÉ

DG SANTÉ is relevant to EBMT because it issued the Directives on safety and quality of tissues and cells. The Public Health Programme funded JACIE in its early stages and EBMT is a participant in a number of projects and joint actions supported by DG SANTÉ.

EBMT is considered a stakeholder organisation interested in participating in ad-hoc meetings with representatives of members of the Competent Authorities on Substances of Human Origin Expert Group. Furthermore, EBMT is a member of the Common representation of Substances of Human Origin's (SoHO) (CoRe SoHO) which brings together EBMT, European Association of Tissue Banks (EATB), European Eye Bank Association (EEBA) and European Blood Alliance (EBA).

EBMT experts have met with Commission staff to help inform discussions around the revision of the Directives. These contacts have also helped to bring specific issues in cell therapy to the attention of the Commission leadership. Summaries of these meetings are published on the DG SANTÉ website.

### European Medicines Agency (EMA)

In 2015 EBMT responded to the EMA Patient Registry Initiative providing details of the Registry. This led to further contacts and an invitation to present at the EMA Patient Registries Initiative meeting in October 2016. In parallel EBMT was also present at the EMA ATMP workshop in May 2016.

EMA is also very interested in the EBMT Registry and its utility for patient follow-up following treatment with CAR-T cells. EBMT participated in the EMA Patients Registries Initiative: CAR-T Cells workshop on 9 February 2018.

### Innovative Medicines Initiative (IMI)

Innovative Medicines Initiative (IMI) is one of the biggest EU funding envelopes. It is based on bringing together stakeholders from the public and private sectors in pursuing different objectives around medicines. Finance is provided by the EU (through HORIZON 2020) while industry makes in-kind contributions e.g. know-how, access to production facilities etc. EBMT's current connection to IMI is as a contributor to the HARMONY Project (Healthcare Alliance for Resourceful Medicine Offensive against Neoplasms in Hematology) which aims to use 'big data' to deliver information that will help to improve the care of patients with these diseases.

In 2016 EBMT responded to the IMI Advanced Therapies Consultation and also attended the annual IMI event in Brussels. Contacts were made with IMI in 2017 as a 'get-to-know-you' effort so that they were aware of our activities although there is nothing of specific interest to EBMT in the current funding calls.

### Health Technology Assessment (HTA)

In late 2017, EBMT opened contacts with a number of national HTA agencies to make them aware of the EBMT Registry.

### Other

The JACIE website recorded 20,875 users compared to 19,609 in 2016, a 6% rise over the previous year. The JACIE Twitter account @JACIE\_EBMT grew to 635 followers.





## EU Transparency Registry

EBMT is registered under 652992023103-09

## EU trademarks

The JACIE name and logo are registered by the EBMT with the European Intellectual Property Office under registration numbers 015063464 and 002967497-0001 respectively.

Eoin McGrath represents EBMT on the External Assessment Board of the Vigilance and Inspection for the Safety of Transfusion, Assisted Reproduction and Transplantation Joint Action ([www.vistart-ja.eu](http://www.vistart-ja.eu)) of the EU. Eoin also participates in the same capacity for the ARTHIQS Joint Action ([www.arthiqs.eu](http://www.arthiqs.eu)). JACIE experts contributed to the new guide to the Quality and safety of tissues and cells for human application published by the European Directorate for the Quality of Medicines and Healthcare (EDQM) which was published in 2017.

We would like to express our appreciation and admiration for the Inspectors, JACIE Committee Members, Accreditation, Standards and Quality Manager Committee members, other volunteers and the JACIE Office team for all their tremendous hard work, commitment and dedication.

**Prof. John Snowden**  
Chair, JACIE Committee

**Mr. Eoin McGrath**  
JACIE Operations Manager

## Institutions awarded accreditation in 2017

Ziekenhuis Netwerk Antwerpen (Antwerp, Belgium); UZ Brussels (Brussels, Belgium); Grand Hôpital de Charleroi (Charleroi, Belgium); CHU UCL Namur (Yvoir, Belgium); Turku University Central Hospital (Turku, Finland); CHU Amiens (Amiens, France); CHRU Besançon & EFS Bourgogne Franche-Comté (Besançon, France); CHU Brest & Etablissement Français du Sang (Brest, France); CHU Estaing of Clermont Ferrand (Clermont Ferrand, France); CHU Limoges & EFS – Aquitaine Limousin (Limoges, France); Hospital TENON - Assistance Publique-Hopitaux de Paris (Paris, France); Insitute for Transfusion Medicine Dessau (Dessau-Roßlau, Germany); Center for Pediatrics and Adolescent Medicine, Medical Center University of Freiburg (Freiburg, Germany); Universitätsklinikum Freiburg (Freiburg, Germany); Bayerische Stammzellbank gGmbH (Gauting, Germany); Einrichtung für Transfusionsmedizin am Universitätsklinikum Halle (Halle, Germany); Universitätsklinikum Halle (Halle, Germany); Universitätsklinikum Hamburg-Eppendorf (Hamburg, Germany); Staädtisches Klinikum Karlsruhe (Karlsruhe, Germany); Universitätsklinikum Magdeburg A. ö. R (Magdeburg, Germany); Klinik für Kinder- und Jugendmedizin -Pädiatrische Hämatologie und Onkologie- Universitätsklinikum Münster (Münster, Germany); DRK-Blutspendedienst NSTOB Institut Bremen-Oldenburg (Oldenburg, Germany); Azienda Ospedaliera Papa Giovanni XXIII (Bergamo, Italy); Azienda Sanitaria dell'Alto Adige (Bolzano, Italy); Azienda Spedali Civili Brescia (Brescia, Italy); Ospedale Civile di Civitanova Marche Area Vasta 3 Marche (Civitanova Marche (Macerata), Italy); Azienda Ospedaliera Universitaria di Ferrara (Ferrara, Italy); Dipartimento Oncologico III La Maddalena (Palermo, Italy); Fondazione IRCCS Policlinico San Matteo (Pavia, Italy); Fondazione IRCCS Policlinico San Matteo (Pavia, Italy); Fondazione IRCCS Policlinico San Matteo (Pavia, Italy); Azienda Ospedaliera di Perugia (Perugia, Italy); Azienda Ospedaliera Regionale San Carlo (Potenza, Italy); Ospedale Pediatrico Bambino Gesù (Rome, Italy); Policlinico Umberto I (Rome, Italy); Policlinico Umberto I (Rome, Italy); Presidio Ospedaliero "S.G. Moscati" (Taranto, Italy); Ospedale San Bortolo - Vicenza (Vicenza, Italy); American University of Beirut Medical Center (Beirut, Lebanon); Medisch Spectrum Twente (Enschede, Netherlands); Radboud University Nijmegen Medical Centre (Nijmegen, Netherlands); Erasmus MC (Rotterdam, Netherlands); Princess Máxima Center (Utrecht, Netherlands); King Faisal Specialist Hospital & Research Centre (Riyadh, Saudi Arabia); Singapore General Hospital (Singapore, Singapore); Institut Català d'Oncologia - Badalona (Badalona, Spain); Hospital Universitario de Gran Canaria Dr. Negrín (Gran Canaria, Spain); Hospital General Universitario Gregorio Marañón (Madrid, Spain); HOSPITAL UNIVERSITARIO DE LA PRINCESA (Madrid, Spain); Hospital Universitario Fundación Jiménez Díaz IDC Salud (Madrid, Spain); Hospital Universitario Ramon y Cajal (Madrid, Spain); Hospital Universitario Virgen Del Rocío (Sevilla, Spain); Hospital Clinico Universitario de Valencia (Valencia, Spain); Drottning Silvias Barn och Ungdomssjukhus (Göteborg, Sweden); Karolinska University Hospital, Huddinge (Stockholm, Sweden); Akademiska Sjukhuset (Uppsala, Sweden); Luzerner Kantonsspital (Luzern, Switzerland); Universitätsspital Zürich (Zürich, Switzerland); Baskent University Adana Hospital, Teaching and Medical Research Center (Adana, Turkey); Gloucestershire Hospitals NHS Foundation Trust (Cheltenham, United Kingdom); Dudley Group of Hospitals NHS Trust (Dudley, United Kingdom); Western General Hospital & Scottish National Blood Transfusion Service (SNBTS) (Edinburgh, United Kingdom); Barts Health NHS Trust (London, United Kingdom); St. George's University Hospitals NHS Foundation Trust (London, United Kingdom); Central Manchester University Hospitals NHS Foundation Trust (Manchester, United Kingdom); Royal Manchester Children's Hospital (Manchester, United Kingdom); The Christie NHS Foundation Trust (Manchester, United Kingdom); John Radcliffe Children's Hospital (Oxford, United Kingdom); NHS Blood and Transplant (Oxford, United Kingdom); Oxford University Hospitals NHS Trust / Buckinghamshire Healthcare NHS Trust (Oxford, United Kingdom); Biovault Technical Ltd (Plymouth, United Kingdom); The Great Western Hospital NHS FT (Swindon, United Kingdom);

Full list available at [www.jacie.org/accredited-centres](http://www.jacie.org/accredited-centres)