EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 May 2010
EMA/241053/2010
Human Medicines Development and Evaluation

European network of paediatric research (EnprEMA)

Recognition criteria for self assessment

The European Medicines Agency is tasked with developing a European paediatric network of existing national and European networks, investigators and centers with specific expertise in the performance of studies in the paediatric population.

Following a test pilot phase, public consultation and the outcome of the second workshop with participants of 28 networks and/or clinical trial centres in March 2010, recognition criteria have been finalised which will have to be fulfilled by existing networks to become a member of the European paediatric network. All networks wishing to become a member of EnprEMA are invited to perform self-assessment and to send the filled-in document to the European Medicines Agency.

The document should be sent to Merja.Heikkurinen@ema.europa.eu

END OF SELF-ASSESSMENT PERIOD	31 July 2010

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An agency of the European Union

EnprEMA

European network of paediatric research at the European Medicines Agency

Recognition criteria for self-assessment

The European Paediatric Regulation (EC) No 1901/2006, as amended, calls for the fostering of high-quality ethical research on medicinal products for use in children. This should be achieved through efficient inter-network and stakeholder collaboration. To meet this objective, a European paediatric research network is to be formed of national and European networks, investigators and centres with specific expertise in performing drug trials in the paediatric population. General information can be found at:

http://www.emea.europa.eu/htms/human/paediatrics/network.htm

Minimum criteria that have to be fulfilled to be recognised as a member of the EnprEMA

This document defines 6 criteria with several subcategories (items) for self-assessment. The criteria and their items have been set up in a public process. Minimum criteria were defined that networks should fulfil to be recognised as a member of the EnprEMA. The defined minimum criteria are flagged with a superscript "**M**".

Irrespective of whether or not only minimum criteria / items are fulfilled, the full list of the criteria and items as well as the network identification should be completed to the extent possible.

Use of the document and application of the recognition criteria

The criteria should be reported for the highest level that the network currently attains. Networks should report on the status of the network, not on individual investigators or sites. For the purpose of this document, the highest level is called the reporting party.

The document should be filled in by the reporting party (once only per network), taking into account the guidance text provided for the various items within the respective criterion. For transparency in general and to permit public scrutiny of the self-assessment, the completed document should be made public by the reporting party, for example, on their website.

For the same purpose, the reporting party should also make publicly accessible the actual data on which the statements are based. For example, if numbers of paediatric trials are provided, references to clinical trial registration numbers could be made publicly accessible.

The self-assessment should be updated annually.

This document should be sent to the European Medicines Agency; it will be published on the EMA webpage.

Criteria for the recognition of an investigator, site* or network as a member of the EnprEMA*

* only when the investigator or the site is not part of a network

Identification M

Name	Innovative Therapies for Children with Cancer (ITCC)	Include legal address, define acronyms
Type	International Network, Academic European Consortium	Indicate type of reporting party, e.g. national or speciality network. May include short mission statement
Street	114 rue Edouard Vaillant	
Postal code	94805	
Town	Villejuif	
Country	France	
Telephone 1	01-42-11-67-41	
Telephone 2		
Mobile phone		
Fax	01-42-11-49-63	
Web site	http://www.itcc-consortium.org/	If available (see criterion 4)
Email for general enquiries	sara.calmanti@igr.fr	If available (see criterion 4)
Representative (main) contact	---	Include first and second name, email, telephone, address, as far as available
First name	Gilles	
Second name	Vassal	
Telephone	01-42-11-49-47	
Mobile phone	06-26-74-24-61	
Email	gvassal@igr.fr	
Further contact(s)	---	Include first and second name, email, telephone, address, as far as available
First name	Sara	
Second name	Calmanti	
Telephone	01-42-11-67-41	
Mobile phone		
Email	sara.calmanti@igr.fr	
The data in this document are 'current' as of	03/05/2012	Provide the date when the criteria were last updated
State how this document can be accessed by the public	Links on http://www.itcc-consortium.org/; http://www.ema.europa.eu/; asking at secretariat	This should be a link to a webpage, but other means and formats to make public are possible

Description [M]

Year of foundation	2003	Of the network, or of the investigator's or site's specific paediatric research activities
Paediatric age ranges of study participants covered by the network		
Preterm and / or term newborn	☐ Yes ☒ No	Newborn: from birth to less than 28 days of age
Infants from 1 month to less 24 months of age	☒ Yes ☐ No	
Children from 2 years to less than 12 years of age	☒ Yes ☐ No	
Adolescents from 12 years to less than 18 years	☐ Yes ☐ No	
Specialities / Conditions covered	All paediatric malignancies, i.e. haematological malignancies and malignant solid tumors from biology research, pharmacology research and preclinical evaluation to phase I and II trials	ENPREMA will cover a range of different networks, from single speciality trials groups to those covering all paediatrics. If not all areas within one speciality are covered, specify conditions
Multispeciality? Specify		For example, oncology or infectious diseases
Speciality or disease specific? Specify	Paediatric Oncology	For example, cardiology only
Conditions covered? Specify	All paediatric malignancies, i.e. haematological malignancies and malignant solid tumors. from biology research, pharmacology research and preclinical evaluation to phase I and II trials	E.g. hypertension (within cardiology) or asthma (within respiratory diseases)
Procedure / intervention specific? Specify		For example, surgery, organ or stem cell transplantation
Number of collaborating countries	6 List all collaborating countries: Austria (A), France (FR), Germany (D), Italy (IT), The Netherlands (NL), the United Kingdom (UK)	State the number of collaborating countries. Indicate "1" if national; Indicate if Europe, outside of Europe, other……. (describe)

Year of foundation	2003	Of the network, or of the investigator's or site's specific paediatric research activities
Number of collaborating centres	37 clinical investigating centers and laboratories in the following institutions: List all collaborating centres: CCRI, Vienna (AT); La Timone, Marseille (FR); Hopital St Louis, Paris (FR); CHU Nancy (FR); CHU Nantes (FR); Institut Curie, Paris (FR); Centre Léon Bérard, Lyon (FR); Institut Gustave Roussy, Villejuif (FR); Hôpital Trousseau, Paris (FR); Centre Oscar Lambret, Lille (FR); CHU Bordeaux (FR); CHU Toulouse (FR); Olgahospital-Pädiatrisches Zentrum, Stuttgart (D); Zentrum für Kinderheilkunde, Bonn (D); UniversitätKlinikum, Munster (D); UniversitätKlinikum Frankfurt (D); Hannover Medical School (D); Pädiatrische Hämatologie und Onkologie Zentrum für Kinderheilkunde und Jugendmedizin, Freiburg (D); University Medical Center Schleswig-Holstein, Kiel (D); Charité, OHC, Berlin (D); Istituto Ortopedico Rizzoli, Bologna (IT); Azienda Ospedaliera di Padova (IT); Instituto Nazionale Tumori, Milano (IT); Gaslini Institute, Genova (IT); Università La Cattolica, Roma (IT); Ospedale San Gerardo, Monza (IT); AMC, Amsterdam (NL); Erasmus, Rotterdam (NL); Great Ormond Hospital, London (UK); St James University Hosp, Leeds (UK); Alder Hey Children's NHS Foundation Trust, Liverpool (UK); Royal Hospital, Bristol (UK); Children's Hospital, Manchester (UK); Birmingham Children's Hospital (UK); Royal Marsden, London (UK); Yorkhill Hospital, Glasgow (UK); Newcastle University (UK) 9 research laboratories in the following institutions: INSTITUT GUSTAVE ROUSSY (FR); Academisch Medisch Centrum (NL); UNIVERSITY OF NEWCASTLE UPON TYNE (UK); Erasmus MC - Sophia Children's Hospital (NL); THE INSTITUTE OF CANCER RESEARCH (UK); Institut Curie (FR); University	State the number of collaborating centres and provide a list of all collaborating centres (attachment or link possible)

Year of foundation	2003	Of the network, or of the investigator's or site's specific paediatric research activities
Type of activity/studies		
Clinical studies	☒ Yes ☐ No	
Experimental research	☒ Yes ☐ No	
Other activity	- Training and Education in the field of development of new anticancer drugs in children and adolescents - Advice on Anticancer Drug development in pediatric and adolescents oncology for Industry and regulatory authorities - Research in Methodology and Statistics - Development of guidelines and research on ethics, in collaboration with parents	Describe type of activities other than clinical and/or non-clinical studies

Evidence for each criterion

How to provide evidence

1. The evidence for this self-assessment document should be based only on the activity of the network during in the last 5 years.
2. Evidence used in this document should have a reference (e.g., publication, annual or periodic report or internal network document).
3. The self-assessment document is to cover a range of different network types. It is recognised that some networks may not be able to accurately respond to every item. In such circumstances, state why it is not possible to respond.
4. The network is referred to as the "reporting party".

Criterion 1: Research experience and ability

Do not include planned trials, but only ongoing and completed trials.

1.1 Number of completed trials [M] Number of ongoing trials [M]	7 closed trials : 3 phase I, 3 phase II, 1 other 8 ongoing trials : 2 phase I, 6 phase II from April 2012: 11 trials closed 10 on-going http://www.itcc-consortium.org/clinical-trials-registry.php 2 open 7 in preparation	Any interventional clinical trial, whether non-commercial, investigator-initiated, industry-sponsored or commercial, in which the reporting party actively took part. Minimum requirement ([M]): one ongoing or one completed trial.
1.2 Total number of participants actually recruited each year Proportion of eligible participants actually recruited each year Describe way of screening and participant recruitment	70 patients in ITCC trials per year - 3400 patients are newly diagnosed yearly with cancer - 850 patients experience relapse yearly in the 37 clinical investigating centers. Trial proposal to ITCC accreditated Centres who engage themselves to enroll into the study at least 3 patients	Relevant to speciality specific networks. State total recruitment capacity for any interventional clinical trial, whether non-commercial, investigator-initiated, industry-sponsored or commercial, in which the reporting party actively took part. Which strategies or pathways are used to screen and recruit participants?
1.3 Total number of collaborating centres	37	For completed and ongoing (open) paediatric trials. Do not include sites in set-up.
Academic (investigator) initiated studies	---	Studies conducted independently from pharmaceutical companies (no sponsorship and no funding). There is a separate category (below) for industry-funded studies.

1.1 Number of completed trials [M] Number of ongoing trials [M]	7 closed trials : 3 phase I, 3 phase II, 1 other 8 ongoing trials : 2 phase I, 6 phase II from April 2012: 11 trials closed 10 on-going http://www.itcc-consortium.org/clinical-trials-registry.php 2 open 7 in preparation	Any interventional clinical trial, whether non-commercial, investigator-initiated, industry-sponsored or commercial, in which the reporting party actively took part. Minimum requirement ([M]): one ongoing or one completed trial.
1.4 Number of ongoing and completed clinical trials	Absolute number: 6 Proportion of all studies: 40% (6 out of 15))	Paediatric interventional trials of any phase of the pharmaceutical development (phase I to IV, including therapy optimising trials if requiring authorisation by regulatory authority) (for other Paediatric trials unrelated to drug development see below)
1.5 Number of paediatric specialities covered by paediatric trials	only paediatric and adolescent oncology and haematology	Count specialities, without repetition, across all ongoing or completed paediatric trials
1.6 Number of paediatric conditions covered by paediatric trials	- 1 condition = cancer - more than 20 different diseases (accrual in phase I is open to any histological type)	If not all areas within one speciality covered count conditions, without repetition, across all ongoing or completed paediatric trials
1.7 Number of other ongoing research studies / programs	- One EU FP6 funded intergated project : the Kids Cancer Kinome Project (identifying and validating druggable targets for 6 paediatric malignancies) - 5 ongoing preclinical evaluation studies on in vitro and in vivo paediatric tumour models	For example, epidemiological studies, outcome studies, translational research in which the reporting party is participating Include cohort studies but not audits. Research is defined as a project with a specific research question in which

1.1 Number of completed trials [M] Number of ongoing trials [M]	7 closed trials : 3 phase I, 3 phase II, 1 other 8 ongoing trials : 2 phase I, 6 phase II from April 2012: 11 trials closed 10 on-going http://www.itcc-consortium.org/clinical-trials-registry.php 2 open 7 in preparation	Any interventional clinical trial, whether non-commercial, investigator-initiated, industry-sponsored or commercial, in which the reporting party actively took part. Minimum requirement ([M]): one ongoing or one completed trial.
		the participant/family provides formal consent.
1.8 Indicate the proportion of public funding	Proportion of academic initiated studies: 40% of studies are academia sponsored Proportion of budget: 40% of their budget (as a whole) is from public finding	Indicate the proportion of the budget handled for completed and ongoing paediatric trials that is derived from public funding sources such as governmental programs, competitive public grants, university contributions
1.9 Number of registered study participants (all studies)		
Industry-sponsored trials	---	
1.10 Number of ongoing and completed trials	9	Paediatric interventional trials of any phase of the pharmaceutical development (phase I to IV, including therapy optimising trials if requiring authorisation)
1.11 Number of paediatric specialities covered by paediatric trials	only paediatric and adolescent oncology and haematology	Count specialities, without repetition, across all ongoing or completed paediatric trials
1.12 Number of paediatric conditions covered by paediatric trials	- 1 condition = cancer - more than 20 different diseases (accrual in phase I is open to any histological type)	If not all areas within one speciality covered count conditions, without repetition, across all

1.1 Number of completed trials [M] Number of ongoing trials [M]	7 closed trials : 3 phase I, 3 phase II, 1 other 8 ongoing trials : 2 phase I, 6 phase II from April 2012: 11 trials closed 10 on-going http://www.itcc-consortium.org/clinical-trials-registry.php 2 open 7 in preparation	Any interventional clinical trial, whether non-commercial, investigator-initiated, industry-sponsored or commercial, in which the reporting party actively took part. Minimum requirement ([M]): one ongoing or one completed trial.
		ongoing or completed paediatric trials
1.13 Number of registered study participants (all studies)	All clinical studies have a Eudract number and are registered on NCI clinical trial .gov	

Criterion 2: Network organisation and processes

2.1 Existence of an identified contact person for external enquiries [M]	☒ Yes ☐ No Comments: The contact person for any question is Sara Calmanti (sara.calmanti@igr.fr) who is in charge of the ITCC website and then dispatches to the relevant ITCC people.	Enquiries from patients, parents, organisations, researchers, pharma-ceutical companies or regulatory authorities are co-ordinated or answered by a nominated contact person. Provide contact details in section "Identification" above.
2.2 Existence of an internal steering committee [M]	☒ Yes ☐ No Comments: - The Clinical Trial Committee steers the clinical activity - The Biolgy committee steers the biology and preclinical evaluation activity - The Accreditation and Quality committee runs the quality and accreditation programm - The Training and Education committee runs the training programm	Minimum requirement ([M]): either an internal steering committee (2.2) or an external advisory / steering committee (2.3).
2.3 Existence of an external advisory / steering committee directing the reporting party [M]	☒ Yes ☐ No Comments: The Executive Committee defines and implements the strategy of the network and coordinates all activities towards the network goals	Minimum requirement ([M]): either an internal steering committee (2.2) or an external advisory / steering committee (2.3).
2.4 Existence of a website	☒ Yes ☐ No Comments: http://www.itcc-consortium.org	If available, mention in "identification" above
2.5 Existence of newsletter	☒ Yes ☐ No Comments: - a internal newsletter for members (currently 1 every 3 months) - a newsletter for partners and stakeholders (once a year)	Newsletter of any format (electronic, surface mail), distributed actively to selected recipients.

2.1 Existence of an identified contact person for external enquiries [M]	☒ Yes ☐ No Comments: The contact person for any question is Sara Calmanti (sara.calmanti@igr.fr) who is in charge of the ITCC website and then dispatches to the relevant ITCC people.	Enquiries from patients, parents, organisations, researchers, pharma-ceutical companies or regulatory authorities are co-ordinated or answered by a nominated contact person. Provide contact details in section "Identification" above.
2.6 Existence of an internal database(s) for disease, condition, treatment and / or outcome [M] If yes, please describe	☒ Yes ☐ No Comments / description: - A database for each trial is created by the Clinical Trial Unit of the Academia sponsor or by the Industry (or outsourced to a CRO). - A database of ITCC trials portfolio (closed, open, in preparation trials, letters of intent) is update regularly.	For example, data base or disease registry to facilitate planning or conducting future trials (may or may not contain individual patient data)
2.7 Provisions to ascertain data protection and data security [M]	☒ Yes ☐ No Comments: GCP are applied to each trial, whatever the sponsor is (academia or industry). The accreditation programm evaluates the capacity of each investigating center to comply to GCP. The academia sponsors (currently Institut Gustave Roussy and Erasmus) have implemented a data protection and safety policy.	Are provisions in place to ascertain patients' /study participants' data protection and data safety within network
2.8 Procedure(s) to access the database by third parties	☒ Yes ☐ No Comments:	Are provisions in place that data can be shared for planning, conducting or analysing a trial(s)?
2.9 Access to external databases /registries	☐ Yes ☒ No Comments:	For example, national databases that are not publicly accessible but to which the reporting party has open or privileged access; database(s) immediately relevant to area and / or scope

2.1 Existence of an identified contact person for external enquiries [M]	☒ Yes ☐ No Comments: The contact person for any question is Sara Calmanti (sara.calmanti@igr.fr) who is in charge of the ITCC website and then dispatches to the relevant ITCC people.	Enquiries from patients, parents, organisations, researchers, pharma-ceutical companies or regulatory authorities are co-ordinated or answered by a nominated contact person. Provide contact details in section "Identification" above.
2.10 Standardised process to access an external database(s)	☐ Yes ☒ No Comments:	Is a standardised process in place to access external/ national databases?

Criterion 3: Scientific competencies and capacity to provide expert advice

3.1 Number of peer-reviewed publications in the last 5 years Provide exact reference(s) Describe the network's contribution to publication(s)	4 Geoerger et al. The selective VEGFR1-3 inhibitor axitinib (AG-013736) shows antitumor activity in human neuroblastoma xenografts has been accepted for publication in the International Journal of Cancer Zwaan CM, et al. The role of the 'innovative therapies for children with cancer'(ITCC) European consortium. Cancer Treat Rev. 2010 Jun;36(4):328-34. Geoerger B, et al. Target-driven exploratory study of imatinib mesylate in children with solid malignancies by the Innovative Therapies for Children with Cancer (ITCC) European Consortium. Eur J Cancer. 2009 Sep;45(13):2342-51. Petain A, et al; on behalf of the Innovative Therapies with Children with Cancer European consortium. Population pharmacokinetics and pharmacogenetics of imatinib in children and adults. Clin Cancer Res 2008 Nov 1;14(21):7102-7109 Two further publications are currently under revision. The publication is the contribution of the network in terms of dissemination of results of the trials run and conducted by ITCC and for informing of its policies	The publications should indicate that they are related to and reference the reporting party.

3.2 Number of competitive grants obtained in the last 5 years	- The FP6 funded Kids Cancer Kinome Projet (2006 - 2010) - The FP7 funded O3K project (oral off-patent oncology drugs for kids (2008 - 2012) - The FP7 funded project EPOC coordinated by Alan Boddy, http://www.epocstudy.org/trial/epoc/documents.aspx) 4 grants from national programms to fund academia sponsored clinical trials.	Grants obtained by reporting party (exclusively or not).
3.3 Access to expert groups M	☒ Yes ☐ No Comments: - The individual members of the ITCC network form a group of experts in the field of paediatric oncology/haematology and new drug development, including biology, pharmacology and methodology - The ITCC network has established joint programms and collaboration with the European paediatric tumour groups which are in charge of late phase II and phase III trials (e.g. SIOPEN, IBFM, EpSSG, SIOPE-Brain,….). Full Paediatric Investigation Plans can thus be designed and delivered, up to phase III. - The ITCC will develop its activity within the frame of the FP7 ENCCA network of excellence (European Network for Cancer research in Children and Adolescents) that will be launched Q1 2011.	Indicate if the reporting party has specific access to established expert groups, such as learned societies

3.4 Capacity to answer external scientific questions [M]	☒ Yes ☐ No Comments: ITCC provides advice and expertise for external scientific questions. The process is to contact Louis Viviers, ITCC Executive Director, at louis.viviers@igr.fr From April 2012: the process has changed: the Chairmen of the ITCC Committees have to be contacted according to the nature of the question. Birgit Geoerger (chair of the Clinical Trial Committee,) Bruce Morland (chair of the Accreditation and Quality Committee), Riccardo Riccardi (chair of the Training and Education Committee), Huib Caron (chair of the Biology Committee)	Indicate if coordinated capacity (staff, process) is available to answer external scientific questions in relation to clinical trials during daily business.
Standardized procedures for assessment of:	---	
3.5 Site feasibility	☒ Yes ☐ No Comments: The Accreditation and Quality committee evaluates the capacity of member institution to participate to ITCC trials. Site feasibility is being run by the sponsor (either industry or academia)	This concerns the suitability of a site for conducting a given trial
3.6 Participant recruitment	☒ Yes ☐ No Comments: Monitoring of recruitment is performed by the Clinical Trial Unit of the Academia sponsors.	This concerns provisions to regularly monitor recruitment progress for a trial.
3.7 Budget calculation for studies	☒ Yes ☐ No Comments: Performed for each trial and negotiated with the pharmaceutical company.	This concerns, for example, quotes and prospective financial planning for a trial.

Criterion 4: Quality management

4.1 Documented adherence to Good Clinical Practice (GCP) guideline [M]	☒ Yes ☐ No Comments: All clinical studies run within ITCC are conducted in compliance with the EU Directive 2001/20/EC and with Good clinical practice.	Declare whether studies conducted comply with the EU Directive 2001/20/EC on Clinical Trials.
4.2 Documented adherence to the ethical considerations for clinical trials in children [M]	☒ Yes ☐ No Comments: http://www.itcc-consortium.org/index.php?p_id=48&p_mode=preview&p_key=AAABADAA	Indicate if documented data / information are publicly available on implementation of / provisions for special ethical requirements for the paediatric trial(s) according to the document "Ethical considerations for clinical trials on medicinal products conducted with the paediatric population".
4.3 Documented adherence to ethical considerations	☒ Yes ☐ No Comments: Approval by an independent ethics committee is requested for all studies in the different participating member states, according to national laws. Not all ethics committee have paediatric expertise in Europe.	Declare whether reporting party requests approval by an independent ethics committee with paediatric expertise for all studies conducted.
4.4 Availability of Standard Operation Procedures (SOP)	☒ Yes ☐ No If yes, provide reference to available SOPs SOPs are available regarding the sponsoring and management of academia-sponsored clinical trials	Indicate existence of SOP e.g. for study management, adverse events reporting etc.
4.5 Capacity to monitor studies (academic trials, industry sponsored trials) [M]	☒ Yes ☐ No Comments: On-site source data verification is performed by the institution in charge of a Academia-sponsored ITCC trial. Study monitoring of industry sponsored trial is performed by the Sponsor or outsourced to a CRO.	Indicate if the reporting party implements the monitoring of paediatric trials according to ICH 6 Good Clinical Practice Guideline.

4.1 Documented adherence to Good Clinical Practice (GCP) guideline M	☒ Yes ☐ No Comments: All clinical studies run within ITCC are conducted in compliance with the EU Directive 2001/20/EC and with Good clinical practice.	Declare whether studies conducted comply with the EU Directive 2001/20/EC on Clinical Trials.
4.6 Capacity to monitor performance of collaborating centres	☒ Yes ☐ No Comments: This is performed by the Accrediation and Quality committee. In particular, number of patients per year and per center, as well as quality of data in academia sponsored trials are monitored.	Indicate if the reporting party implements the monitoring of performance of collaborating centres.
4.7 Quality control and quality assurance, traceability and data safety M	☒ Yes ☐ No Comments:	Indicate if this is implemented in the reporting party's remit.

Criterion 5: Training and educational capacity to build competences

5.1 Evidence of collaboration with regulatory authorities [M]	☒ Yes ☐ No Comments: - ITCC members contributed to the Paediatric Addendum of the EMA guidance for the development of anticancer drugs in human (CPMP/EWP/569/02 July 2003) - ITCC members are members of the EMA Task force in Paediatric Oncology, which is co-chaired by the ITCC president - ITCC members were member of the EMA Committee on Orphan Medical Products Several ITCC members are experts for the CHMP.	Indicate awareness of regulatory requirements for developing medicines; for example, implementation of guidelines from regulatory authorities.
5.2 Capacity to provide competent consultation to regulatory authorities	☒ Yes ☐ No Comments: ITCC has the expertise in all fields of paediatric oncology and haematology to provide compentent consultation to regulatory authorities.	Indicate the capacity of the reporting party to provide expert advice to regulatory authorities. For example, nominations into standing scientific committees to regulatory authorities, registration(s) as authorities' external expert(s).
5.3 Formal meetings for clinical trials If yes, provide number	☒ Yes ☐ No Comments: - for each clinical trial, an investigator meeting is being held at least once a year. - the clinical trial committee has 4 conference call once a month to monitor the portfolio of ITCC trials (open trials, trials in preparation, letters of intent) - one General Assembly meeting is held each year.	For example, investigator meetings, trainings specific to a given ongoing or planned trial.

5.4 Training courses given over the last 2 years [M] If yes, provide number	☒ Yes ☐ No Comments: An ITCC training course is organized by ITCC every 18 months to 2 years - 1st ITCC Training Days (March 5-8, 2008, Orta San Giulio, Italy) - 2nd ITCC Training Days (October 22-24, 2009 Catholic University, Rome, Italy) ITCC members give lessons on new drug development in several Training courses in Paediatric Oncology, such as those of the European School of Oncology and the Amsterdam School of Paediatric Oncology. From 2012: 1. Training Days 2012 -> 12-14 September, 2012 Roma, Italy http://www.itcc-consortium.org/training-days-2012.php 2. Optimising Standards in ITCC Centres Workshop -> 17 October 2012	For example, training specific to a trial or in general for trial(s), with external participants or from the reporting party. Minimum requirement (M): training courses either given (5.4) or received (5.5).
5.5 Training courses received over the last 2 years [M] If yes, provide number	☒ Yes ☐ No Comments: many	For example, training specific to a trial or in general for trial(s), with external participants or from the reporting party. Minimum requirement (M): training courses either given (5.4) or received (5.5).
5.6 Promotion of participation in clinical trials in countries with limited resources Provide list of countries	☐ Yes ☒ No Comments: For the time being, early drug trials are implemented in a limited number of centers and countries	Indicate if support for such trials is provided by the reporting party.

Criterion 6: Public involvement M

Minimum requirement (M): involvement in at least one of the below items.

6.1 Involvement of patients, parents or their organisations in the protocol design	☒ Yes ☐ No Comments: Parents gathering into a Charity asked to review the protocol of academia-sponsored trials.	Indicate if public stakeholders are /have been involved
6.2 Involvement of patients, parents or their organisations in creating the protocol information package	☒ Yes ☐ No Comments: Parents gathering into a Charity are asked to review the information package of industry and academia sponsored trials.	Indicate if public stakeholders are /have been involved
6.3 Involvement of patients, parents or their organisations in the prioritisation of needs for clinical trials in children	☒ Yes ☐ No Comments: The International Confederation of Childhood Cancer Parents Organisations is a partner of ITCC. Parents are partners of the EU project that are submitted, when clinical research activity is part of the proposal	Indicate if public stakeholders are /have been involved