EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 February 2012
EMA/4572/2012
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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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	International BFM Study Group (I-BFM-SG)	Include legal address, define acronyms
Type	Network of National Study Groups for the treatment of hematological malignancies Mission •To foster the information exchange among the participating groups, including preliminary results. •To promote research projects in childhood leukemias and related disorders, including non-Hodgkin's lymphomas. •To activate cooperative projects for biological research. •To study rare problems. •To promote prospective randomized clinical trials, using consensus approaches and allowing the participation of other groups. •To define, detect, register and possibly prevent acute toxicity and late effects	Indicate type of reporting party, e.g. national or speciality network. May include short mission statement
Street	University Medical Center Schleswig-Holstein, Campus Kiel -Schwanenweg 20 (* address of the present Chairman of the I-BFM SG)	
Postal code	24105	
Town	Kiel	
Country	Germany	
Telephone 1	0049 - 431 - 597 - 1621	
Telephone 2		
Mobile phone		
Fax	0049 - 431 - 597 - 3966	
Web site	www.bfm-international.org	If available (see criterion 4)
Email for general enquiries	schrappe-ibfm@pediatrics.uni-kiel.de	If available (see criterion 4)

Representative (main) contact	---	Include first and second name, email, telephone, address, as far as available
First name	Professor Martin Schrappe, MD - Chairman of the I-BFM SG -	
Second name		
Telephone	0049 - 431 - 597 - 1621	
Mobile phone		
Email	m.schrappe@pediatrics.uni-kiel.de	
Further contact(s)	---	Include first and second name, email, telephone, address, as far as available
First name	Professor Andrea Biondi, MD - Contact for EnprEMA -	
Second name		
Telephone	0039-039-2333515	
Mobile phone	0039-039-3474513638	
Email	abiondi.unimib@gmail.com	
The data in this document are 'current' as of	22/02/2012	Provide the date when the criteria were last updated
State how this document can be accessed by the public	www.bfm-international.org	This should be a link to a webpage, but other means and formats to make public are possible

Description [M]

Year of foundation	1988	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	Hematological malignancies	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	Oncology	For example, oncology or infectious diseases
Speciality or disease specific? Specify	Hematological malignancies	For example, cardiology only
Conditions covered? Specify	Childhood leukemias and related disorders, including non-Hodgkin's lymphomas.	E.g. hypertension (within cardiology) or asthma (within respiratory diseases)
Procedure / intervention specific? Specify	Chemotherapy Stem cell transplantation Immunotherapy	For example, surgery, organ or stem cell transplantation

Number of collaborating countries	32: 26 within Europe, 6 outside Europe List all collaborating countries: 1. Europe •Austria (BFM-A) •Belgium (CLCG-EORTC) •Croatia •Czech Republic (CLWP) •Denmark (NOPHO) •Finland (NOPHO) •France (FRALLE, CLCG-EORTC) *Greece (HESPHO) •Germany (BFM-G) •Hungary (HPOG) •Iceland (NOPHO) •Israel (INS) •Italy (AIEOP) •Norway (NOPHO) •Poland (PPLLSG) *Portugal (CLCG-EORTC) •Serbia and Montenegro •Slovakia •Slovenia *Spain (PETHEMA, SHOP) •Sweden (NOPHO) •Switzerland (BFM-CH) •The Netherlands (DCOG) •Turkey •Unit. Kingdom (UKCCLG) •Ukraine 2. Outside Europe •Argentina (GATLA) •Chile (PINDA) •Hong-Kong •Israel (INS) •Japan (JPLSG, JACLS) •Uruguay	State the number of collaborating countries. Indicate "1" if national; Indicate if Europe, outside of Europe, other……. (describe)

Number of collaborating centres	The precise number of collaborating centers is not available but can be considered in the range of several hundreds (e.g. 38 sites for Italy-AIEOP and more than 50 sites for Germany-BFM-G). Number of sites can be obtained through the National study groups. List all collaborating centres: see above	State the number of collaborating centres and provide a list of all collaborating centres (attachment or link possible)
Type of activity/studies		
Clinical studies	☒ Yes ☐ No	
Experimental research	☒ Yes ☐ No	
Other activity	1.Continuous education through the organization of the Annual Meeting (> 300 participants), several Committees meetings and a Biennial Symposium on Childhood Leukemias; 2. Promote the cooperation with countries with limited reosurces through the organization of international clinical studies. 3. Work on special aspects of childhood leukemia and lymphoma in committees. Currently, the following Committees are active: ALL, AML, Biology and Diagnosis, Stem Cell Transplantation, CML, Early Clinical Trials, Early and Late Toxicity and Education, Information Management and Methodology, NHL, Resistant Disease.	Describe type of activities other than clinical and/or non-clinical studies

Evidence for each criterion

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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]	10 completed trials, 11 ongoing trials 1.Completed studies ALL: 1.1. IDH (1991-1995): SR ALL (355) 1.2 Pulses (1995-2000): MR ALL (2618) 1.3. HSCT in VHR ALL (1995-2000) (357) 1.4. AIEOP-BFM ALL (2000-2006): ALL (4827) 1.5. Interfant-99 (1999-2006): ALL below the age of one year (ALL<1y) (482) 1.6. EsPhALL* (2004-2009): ALL positive for the t(9;22) translocation (181) 2. Ongoing studies ALL: 2.1 ALLIC-BFM 2002 (2002-2009): Randomized clinical protocol for ALL in countries with limited resources 2.2 Interfant-06: Randomized clinical trial for ALL under 1y*(2007-) 2.3 ALL-SCT BFM 2003: HSCT* in VHR ALL (2003-) 2.4 AIEOP-BFM ALL 2009 (2009-): Randomized clinical trial for ALL (age 1-18y) 2.5 EsPhALL"bridge"study (2010-) *web-based trials 3. Completed studies AML: 3.1 Relapsed AML 2001/01 (2001-2009) 4. Ongoing studies AML: 4.1 ICC APL Study 01 (2008-) 4.2 Down Syndrome ML 2006 (2006-)	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.

	5. Completed studies NHL: 5.1 NHL-BFM 90 (1990-95; 650 patients) 5.2 NHL-BFM 95 (1995-2004; 1337 patients 5.3 EURO-LB 02 (2004-2008) 6. Ongoing studies NHL: 6.1 B-NHL BFM 04 (2004-) 6.2. B-NHL BFM Rituximab (2004-) 6.3 ALCL 99 (2000-) 6.4 ALCL-Relapse (2004-)	
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	see above (full recruitment) Participation to the study is based on the decision of the National Study Group. According to that, the proportion of eligible patients is >90%. In some member countries, participation in clinical trials is population-based. Comparison of data bases with cancer registries allows to define degree of coverage for each entity.	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	depending on individual clinical trial	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.
1.4 Number of ongoing and completed clinical trials	Absolute number: 21 (10 completed, 11 ongoing)	Paediatric interventional trials of any phase of the pharmaceutical

	Proportion of all studies: 100%	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	Hematological malignancies	Count specialities, without repetition, across all ongoing or completed paediatric trials
1.6 Number of paediatric conditions covered by paediatric trials	6: ALL, AML, APL, CML, Non-Hodgkin Lymphoma (NHL), hematopoetic stem cell transplantation	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	Examples of research projects that benefit from the network: Down Syndrome ALL MRD in leukemia Molecular characteristics of very high risk ALL MLL leukemias (a subgroup between ALL and AML?) Notch1 mutations in T-ALL Genetic variation in ALL	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 the participant/family provides formal consent.
1.8 Indicate the proportion of public funding	Proportion of academic initiated studies: >90% Proportion of budget: >90% derived from governmental programs and support by charities and private foundations (differences in the proportion depend by countries)	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)	8820 (only refers to closed studies in ALL patients)	
Industry-sponsored trials	---	
1.10 Number of ongoing and completed trials	The I-BFM-SG does not run such trials as organization. Under the umbrella of the consortium, trials related to drug development (Phase I/II) are run by member institutions (clinical centers in	Paediatric interventional trials of any phase of the pharmaceutical development (phase I to IV, including therapy optimising

	different countries). Some of these centers within the I-BFM network are also accredited members of the ITCC, and have been involved in phase I/II studies.	trials if requiring authorisation)
1.11 Number of paediatric specialities covered by paediatric trials	Hematological malignancies	Count specialities, without repetition, across all ongoing or completed paediatric trials
1.12 Number of paediatric conditions covered by paediatric trials	6: ALL, AML, APL, CML, Non-Hodgkin Lymphoma, hematopoetic stem cell transplantation	If not all areas within one speciality covered count conditions, without repetition, across all ongoing or completed paediatric trials
1.13 Number of registered study participants (all studies)	Number of patients enrolled is not available from the I-BFM network but only directly from the member institutions involved.	

Criterion 2: Network organisation and processes

2.1 Existence of an identified contact person for external enquiries [M]	☒ Yes ☐ No Comments: Contacts (see "Identification" above): I-BFM-SG Office and Website Prof. Martin Schrappe as Chairman elected by the I-BFM-SG Executive Board Prof. Andrea Biondi as EnprEMA contact person elected by the Executive Board of the I-BFM-SG Chairs of disesase committees (requests will be forwarded by the I-BFM-SG office).	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 I-BFM-SG has an Executive Board. Each clinical study group has an internal trial steering committee.	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: An International data Monitoring Safety Committee (DMSC) is a requirement of all I-BFM-SG clinical studies.	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: see "Identification" above	If available, mention in "identification" above
2.5 Existence of newsletter	☒ Yes ☐ No Comments: There is regular communication within the Executive Board, and within Disease Committees. Study Groups issue regular (annual) study progress reports. For the Annual Meeting of I-BFM-SG, progress reports of clinical trials and disease/research committees are collected and distributed to participants of the Annual Meeting.	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: Contacts (see "Identification" above): I-BFM-SG Office and Website Prof. Martin Schrappe as Chairman elected by the I-BFM-SG Executive Board Prof. Andrea Biondi as EnprEMA contact person elected by the Executive Board of the I-BFM-SG Chairs of disesase committees (requests will be forwarded by the I-BFM-SG office).	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: Clinical trial groups have data bases according to requirements of GCP. There is no general registry, but retrospective analyses or metaanalysis of different treatment strategies for disease entities (or special subgroups) comprised by the I-BFM network are performed among members of the I-BFM-SG, e.g. to design new studies (e.g. Interfant-06 study). Randomized clinical trials are analyzed according to established standard procedures. Meta-analyses are also performed together with the "Ponte di Legno International ALL Consortium". Clinical trial groups often serve also as National Reference centers, and provide expert opinion and diagnostics.	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: Patient's data protection are assured by each National Study Group.	Are provisions in place to ascertain patients' /study participants' data protection and data safety within network

2.1 Existence of an identified contact person for external enquiries [M]	☒ Yes ☐ No Comments: Contacts (see "Identification" above): I-BFM-SG Office and Website Prof. Martin Schrappe as Chairman elected by the I-BFM-SG Executive Board Prof. Andrea Biondi as EnprEMA contact person elected by the Executive Board of the I-BFM-SG Chairs of disesase committees (requests will be forwarded by the I-BFM-SG office).	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.
2.8 Procedure(s) to access the database by third parties	☒ Yes ☐ No Comments: Outcome data are shared on demand among member groups and study groups. By-laws for DSMC are in place.	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 treatment of subgroups, data comparison between member groups has been performed. This facilitates faster planning of clinical trials.	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
2.10 Standardised process to access an external database(s)	☒ Yes ☐ No Comments: Some national groups have established procedures of regular data exchange with cancer registries.	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)	A complete data set of all publications directly produced by members of the network can be provided upon request. 24 selected references are reported for the period 2005-2010 (see appendix 1.). The references were selected to highlight recent contributions of the network to the specific area. The publications(s) are the result of: 1. Clinical study reports; 2. Committee activities; 3. Biological and translational research projects born and promoted within the network.	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 research activities of the network are usually funded through National funding agencies or private foundations. Soon, some I-BFM-SG activities will be funded through the ENCCA initiative (FP7 NoE project).	Grants obtained by reporting party (exclusively or not).
3.3 Access to expert groups M	☒ Yes ☐ No Comments: The I-BFM-SG is formally Board member of SIOP-E (European branch of the International Society of Pediatric Oncology). Members of the I-BFM-SG were founding members of the "Ponte-di Legno International ALL Consortium" to promote the research in rare subsets of ALL in children. I-BFM-SG has active cooperations with the "Children's Oncology Group" (USA) and the ITCC (European initiative for "Innovative Therapies for Children with Cancer").	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: The external contacts are managed by the elected Chairman of the I-BFM, or through the acting chairs of the disease committees.	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: Qualification of sites in clinical trials is evaluated by the chairs and members of clinical trial groups.	This concerns the suitability of a site for conducting a given trial
3.6 Participant recruitment	☒ Yes ☐ No Comments: Each clinical trial is managed by a joint steering committee of the different National Study Groups involved in the study. The annual report of each study is presented and discussed during the annual meeting of the I-BFM-SG, and in separate meetings of the trial steering committees.	This concerns provisions to regularly monitor recruitment progress for a trial.
3.7 Budget calculation for studies	☒ Yes ☐ No Comments: The financial support of each study is not managed by the I-BFM-SG network, but through the members of each National Study Group.	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 studies conducted since 2006 (Interfant-06, AIEOP-BFM ALL 2009;ICC APL Study 01) fully adhere to the GCP guideline and the EU Directive 2001/20/EC on Clinical Trials.	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: Studies are only approved at national level if the ethical committees and the National competent authorities have provided consent. Studies have to adhere to the different bylaws and need to comply with the most recent EU directive on ethical considerations for clinical trial in paediatric populations.	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: All national Ethics Commissions include paediatric expertise.	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 Only the most recent clinical studies (see above 4.1) have included SOPs.	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: Only the most recent clinical studies (see above 4.1).	Indicate if the reporting party implements the monitoring of paediatric trials according to ICH 6 Good Clinical Practice Guideline.
4.6 Capacity to monitor performance of collaborating centres	☒ Yes ☐ No Comments: The perfomance of the collaborating centres is monitored through the National Study Groups.	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: The joint trial steering committee with members from the different National Study Groups is fully responsible for the quality control and quality assurance. Establishing an independent DMSC has become common policy of most recent clinical studies performed within the network.	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: Many members of the I-BFM network have been involved in initiatives of the regulatory authorities. The I-BFM-SG chairman is involved in the ENCCA initative which targets to improve conditions for collaborative clinical research in Europe.	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: see above	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: The development of each clinical trial is a stepwise process. It includes several meetings of the steering commitees. Once/twice a year 1-2 meetings of the Disease Committees (i.e ALL, AML…) are organized to update/plan/ discuss the different ongoing research projects, including the clinical studies. The Annual Meeting offers the opportunity for all National delegations to have an update of the entire activity of the network.	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: Training is partly provided through joint teaching efforts with EHA and ESH (regular workshops). Within the I-BFM-SG, the ELTEC (the Early and Late Toxicity and Education Committee of the I-BFM-SG) provides courses and teaching material. For the most recent clinical trial in ALL (i.e AIEOP-BFM ALL 2009) a common two days course was organized to present the study to the representatives of the treating centers. In earlier trials training courses were given not at network level, but at National levels for each specific clinical study.	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: see 5.4	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: The ALL IC-BFM 2002 was one of the most successful examples of a clinical trial in childhood ALL conducted by countries with limited resources. These are regular members of the network (e.g. Argentina, Poland, Chile, Czech Rep., Hungary, Serbia, Hong Kong, Croatia, Slovakia, Uruguay, Ukraine, and Slovenia) or participating groups (Cuba and Moscow). Additional examples are networks for new diagnostic procedures, e.g. genetics, or MRD analysis by PCR or flow cytometry. The network, in particular the German BFM group , has provided the methodological support for study design, data management and analysis in trial ALL-IC BFM 2002.	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: Participation in common sessions at meetings of SIOP with parent groups and (long-term) survivors.	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: Indirectly, by involvement of I-BFM partners in the European ENCCA initiative, which aims to foster collaboration with patient/parent groups (ICCPO) on general issues of information and awareness.	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: Through direct and indirect contacts with parent groups and survivors, studies of late effects have a direct impact on design of clinical trials minimizing acute and long-term toxicity. Indirect involvement, as in some studies (e.g. ALL-Rez), parent organizations are able to provide funding. Also, partners of the ENCCA initiative will collect information on concerns and expectations of patients/parents.	Indicate if public stakeholders are /have been involved