17 February 2012
EMA/77450/2012
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.

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

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| **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 | National Institute for Health Research (NIHR) Medicines for Children Research Network (MCRN)<br><br>MCRN Coordinating Centre<br><br>University of Liverpool Division of Child Health, Alder Hey Children's NHS Foundation Trust, Liverpool L12 2AP UK | Include legal address, define acronyms |
| Type | National network for supporting medicines for children research within England. The NIHR Medicines for Children Research Network supports the development and conduct of randomised controlled trials and other well designed studies of medicines for children, and is part of the National Institute for Health Research (NIHR) Clinical Research Network which is funded by the Department of Health for England | Indicate type of reporting party, e.g. national or speciality network. May include short mission statement |
| Street | University of Liverpool Institute of Translational Medicine (Child Health), Alder Hey Children's NHS Foundation Trust, Eaton Road | |
| Postal code | L12 2AP | |
| Town | Liverpool | |
| Country | United Kingdom | |
| Telephone 1 | 00 44 (0) 151 252 5067 | |
| Telephone 2 | 00 44 (0) 151 282 4711 | |
| Mobile phone | | |
| Fax | 00 44 (0) 151 282 4715 | |
| Web site | http://www.mcrn.org.uk | If available (see criterion 4) |
| Email for general enquiries | info@mcrn.org.uk<br>Industry enquiries - industry@mcrn.org.uk; grip@mcrn.org.uk | If available (see criterion 4) |
| Representative (main) contact | --- | Include first and second name, email, telephone, address, as far as available |
| First name | Mark | |

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|---|---|---|
| Second name | Turner | |
| Telephone | 00 44 (0) 151 795 9558 | |
| Mobile phone | | |
| Email | mark.turner@liv.ac.uk | |
| Further contact(s) | --- | Include first and second name, email, telephone, address, as far as available |
| First name | Barbara | |
| Second name | Richards | |
| Telephone | 00 44 (0) 151 282 4711 | |
| Mobile phone | | |
| Email | grip@mcrn.org.uk | |
| The data in this document are 'current' as of | January 2012 | Provide the date when the criteria were last updated |
| State how this document can be accessed by the public | | This should be a link to a webpage, but other means and formats to make public are possible |

## *Description* M

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| Year of foundation | 2005 | 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 specialties included | 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 | All paediatric specialties included | For example, oncology or infectious diseases |
| Speciality or disease specific? Specify | All paediatric specialties included | For example, cardiology only |

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| Conditions covered? Specify | All paediatric specialties included | E.g. hypertension (within cardiology) or asthma (within respiratory diseases) |
| Procedure / intervention specific? Specify | All paediatric specialties included | For example, surgery, organ or stem cell transplantation |
| Number of collaborating countries | 1 (England) with strong links to other UK nations (Wales, Scotland & Northern Ireland)<br><br>List all collaborating countries:<br>Links to numerous counrtries through GRiP (Global Research in Paediatrics) and other initiatives. | State the number of collaborating countries. Indicate "1" if national; Indicate if Europe, outside of Europe, other……. (describe) |
| Number of collaborating centres | All centres involved in the treatment of children in England, divided across nine geographical regions.<br><br>List all collaborating centres:<br>MCRN Cheshire, Merseyside & North Wales Local Research Network; MCRN Greater Manchester, Lancashire & South Cumbria Local Research Network; MCRN London & South East Local Research Network; MCRN South West Local Research Network; MCRN East Local Research Network; MCRN West Midlands Local Research Network; South Central MCRN Area; North East MCRN Area; East Anglia MCRN Area. | 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 | | 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.

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| 1.1<br>Number of completed trials [M]<br>Number of ongoing trials [M] | 35 studies within the MCRN Portfolio have completed or closed<br><br>158 studies within the MCRN Portfolio are currently open or within set up. The live portfolio database contains accurate up to date study recruitment information: http://public.ukcrn.org.uk/Search/Portfolio.aspx?level1=4 | 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<br>Total number of participants actually recruited each year<br><br>Proportion of eligible participants actually recruited each year<br><br>Describe way of screening and participant recruitment | >8000 participants were recruited to MCRN Portfolio studies within the 2010/11 annual reporting period.<br><br>Due to large number of sites/potential participants, unable to specify accurately<br><br>The MCRN supports active screening and recruitment of children to MCRN Portfolio studies, via participating sites or utilisation of local, regional and national patient databases | Relevant to speciality specific networks.<br>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<br>Total number of collaborating centres | During 2010/11 annual reporting period, children were recruited to MCRN Portfolio studies from over 400 sites within England | 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 | Absolute number: | Paediatric interventional |

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| Number of ongoing and completed clinical trials | 184 RCT, Open label, single arm and diagnosis<br><br>Proportion of all studies:<br>60% | trials of any phase of the pharmaceutical development (phase I to IV, including therapy optimising trials if requiring authorisation by regulatory authority)<br>(for other Paediatric trials unrelated to drug development see below) |
| 1.5<br>Number of paediatric specialities covered by paediatric trials | 20<br>The MCRN aims to include all paediatric specialities | Count specialities, without repetition, across all ongoing or completed paediatric trials |
| 1.6<br>Number of paediatric conditions covered by paediatric trials | Difficult to ascertain the exact number of conditions.<br>The MCRN does not aim to exclude any paediatric conditions | If not all areas within one speciality covered count conditions, without repetition, across all ongoing or completed paediatric trials |
| 1.7<br>Number of other ongoing research studies / programs | 125 | 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<br>Indicate the proportion of public funding | Proportion of academic initiated studies:<br>43% of studies are publicly funded.<br>5% of studies are industry-funded but investigator led.<br>Proportion of budget:<br>Difficult to assess as the funding amounts for industry sponsored studies are unavailable. | 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<br>Number of registered study participants (all studies) | >33,000 | |
| Industry-sponsored trials | --- | |
| 1.10<br>Number of ongoing and completed trials | 137 industry studies adopted by MCRN<br>46 open<br>24 in setup | Paediatric interventional trials of any phase of the pharmaceutical |

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| | 19 in follow up<br>36 closed<br>11 temporarily suspended<br>1 withdrawn during set up | development (phase I to IV, including therapy optimising trials if requiring authorisation) |
| 1.11<br>Number of paediatric specialities covered by paediatric trials | 11 | Count specialities, without repetition, across all ongoing or completed paediatric trials |
| 1.12<br>Number of paediatric conditions covered by paediatric trials | 46 | If not all areas within one speciality covered count conditions, without repetition, across all ongoing or completed paediatric trials |
| 1.13<br>Number of registered study participants (all studies) | 33312 | |

## Criterion 2: Network organisation and processes

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| 2.1<br>Existence of an identified contact person for external enquiries [M] | ☒ Yes ☐ No<br><br>Comments: | 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<br>Existence of an internal steering committee [M] | ☒ Yes ☐ No<br>Comments:<br>MCRN Executive Committee has representation of all consortium member organisations | Minimum requirement ([M]): either an internal steering committee (2.2) or an external advisory / steering committee (2.3). |
| 2.3<br>Existence of an external advisory / steering committee directing the reporting party [M] | ☒ Yes ☐ No<br>Comments:<br>MCRN Board includes representation from all key internal and external stakeholders, including representation from the Department of Health for England | Minimum requirement ([M]): either an internal steering committee (2.2) or an external advisory / steering committee (2.3). |
| 2.4<br>Existence of a website | ☒ Yes ☐ No<br>Comments: | If available, mention in "identification" above |
| 2.5<br>Existence of newsletter | ☒ Yes ☐ No<br>Comments:<br>Quarterly newsletter circulated electronically and available on the MCRN website | Newsletter of any format (electronic, surface mail), distributed actively to selected recipients. |
| 2.6<br>Existence of an internal database(s) for disease, condition, treatment and / or outcome [M]<br><br>If yes, please describe | ☒ Yes ☐ No<br><br>Comments / description:<br>The MCRN Local Research Networks have access to local and regional databases of children with specific diseases or conditions. | For example, data base or disease registry to facilitate planning or conducting future trials (may or may not contain individual patient data) |
| 2.7<br>Provisions to ascertain data protection and data security [M] | ☒ Yes ☐ No<br>Comments:<br>The network complies with national and local policies relating to data protection, patient safety and research governance | Are provisions in place to ascertain patients' /study participants' data protection and data safety within network |

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| 2.1<br>Existence of an identified contact person for external enquiries M | ☒ Yes ☐ No<br>Comments: | 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<br>Procedure(s) to access the database by third parties | ☒ Yes ☐ No<br>Comments:<br>Access to relevant data is available via the MCRN Local Research Networks and Clinical Studies Groups | Are provisions in place that data can be shared for planning, conducting or analysing a trial(s)? |
| 2.9<br>Access to external databases /registries | ☒ Yes ☐ No<br>Comments:<br>The network has access to some external databases/registries through its associates | 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<br>Standardised process to access an external database(s) | ☐ Yes ☒ No<br>Comments:<br>This varies according to the specific database/registry | Is a standardised process in place to access external/ national databases? |

## Criterion 3: Scientific competencies and capacity to provide expert advice

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| 3.1<br>Number of peer-reviewed publications in the last 5 years<br>Provide exact reference(s)<br>Describe the network's contribution to publication(s) | Not applicable - the network is not formally involved in the publication of findings from studies within the MCRN Portfolio, although the network is establishing a process to identify and disseminate publications arising from MCRN Portfolio studies | The publications should indicate that they are related to and reference the reporting party. |
| 3.2<br>Number of competitive grants obtained in the last 5 years | Not applicable - the network does not seek to obtain competitive grants directly | Grants obtained by reporting party (exclusively or not). |
| 3.3<br>Access to expert groups [M] | ☒ Yes ☐ No<br>Comments:<br>The MCRN has established 15 Clinical Studies Groups covering all paediatric specialty areas. These groups are multidisciplinary and include patient representatives in addition to clinical and research expertise | Indicate if the reporting party has specific access to established expert groups, such as learned societies |
| 3.4<br>Capacity to answer external scientific questions [M] | ☒ Yes ☐ No<br>Comments:<br>The MCRN Clinical Studies Groups have a dedicated manager and administrator who coordinates enquiries relating to specific scientific questions in relation to clinical research | 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<br>Site feasibility | ☒ Yes ☐ No<br>Comments:<br>The MCRN operates a standard process for assessing site feasibility across its nine regions, with additional input provided from the other UK nations and Clinical Studies Groups | This concerns the suitability of a site for conducting a given trial |

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| 3.6<br>Participant recruitment | ☒ Yes ☐ No<br>Comments:<br>The MCRN operates a robust performance monitoring process on a monthly basis, utilising recruitment data submitted monthly by Portfolio study teams, with input from the MCRN regions and Clinical Studies Groups. The performance monitoring process is focused on whether studies recruit on time and to target. | This concerns provisions to regularly monitor recruitment progress for a trial. |
| 3.7<br>Budget calculation for studies | ☐ Yes ☒ No<br>Comments:<br>The MCRN is not involved in calculation of budgets for studies but does review available funding when assessing aspects of study feasibility and delivery. Please see NIHR Industry Costing Template - http://www.crncc.nihr.ac.uk/Life+sciences+industry/tools/costing | This concerns, for example, quotes and prospective financial planning for a trial. |

## Criterion 4: Quality management

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| 4.1<br><br>Documented adherence to Good Clinical Practice (GCP) guideline M | ☒ Yes ☐ No<br><br>Comments:<br><br>All studies within the MCRN Portfolio are conducted in compliance with the EU Directive 2001/20/EC on Clinical Trials. The MCRN has access to a comprehensive GCP training programme which is open to all investigators working on MCRN Portfolio studies | Declare whether studies conducted comply with the EU Directive 2001/20/EC on Clinical Trials. |
| 4.2<br>Documented adherence to the ethical considerations for clinical trials in children M | ☒ Yes ☐ No<br>Comments:<br>MCRN Portfolio studies comply with national and international ethical and research governance requirements | 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<br>Documented adherence to ethical considerations | ☒ Yes ☐ No<br>Comments:<br>Studies within the MCRN Portfolio are required to comply with UK ethics requirements. | Declare whether reporting party requests approval by an independent ethics committee with paediatric expertise for all studies conducted. |
| 4.4<br>Availability of Standard Operation Procedures (SOP) | ☒ Yes ☐ No<br>If yes, provide reference to available SOPs<br>MCRN Local Research Networks and the MCRN Clinical Trials Unit operate according to SOPs | Indicate existence of SOP e.g. for study management, adverse events reporting etc. |
| 4.5<br>Capacity to monitor studies (academic trials, industry sponsored trials) M | ☒ Yes ☐ No<br>Comments:<br>This is a core activity of the Clinical Trials Unit that work with the MCRN CC and LRNs/Areas to deliver studies. Other MCRN staff support activities on a case by case basis. | Indicate if the reporting party implements the monitoring of paediatric trials according to ICH 6 Good Clinical Practice Guideline. |

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| 4.6<br>Capacity to monitor performance of collaborating centres | ☒ Yes ☐ No<br>Comments:<br>MCRN regional areas are closely performance monitored, with activity data reported to the MCRN Board and the Department of Health for England twice a year. Each MCRN Local Research Network is required to provide an annual report. | Indicate if the reporting party implements the monitoring of performance of collaborating centres. |
| 4.7<br>Quality control and quality assurance, traceability and data safety[M] | ☒ Yes ☐ No<br>Comments:<br>This is a core activity of the Clinical Trials Unit that work with the MCRN CC and LRNs/Areas to deliver studies. Other MCRN staff support activities on a case by case basis. | Indicate if this is implemented in the reporting party's remit. |

## Criterion 5: Training and educational capacity to build competences

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| 5.1<br>Evidence of collaboration with regulatory authorities [M] | ☒ Yes ☐ No<br>Comments:<br>The UK clinical research regulatory body (MHRA) is represented on the MCRN Board and works closely with the network. Strong links also exist with the EMA. | Indicate awareness of regulatory requirements for developing medicines; for example, implementation of guidelines from regulatory authorities. |
| 5.2<br>Capacity to provide competent consultation to regulatory authorities | ☒ Yes ☐ No<br>Comments:<br>The Network provides expertise when required by regulatory agencies. The Director and several Associate Directors of the MCRN have key roles within national and pan-european regulatory authorities (for example, the MHRA Paediatric Expert Advisory Group, the UK Commission of Human Medicines). | 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<br>Formal meetings for clinical trials<br>If yes, provide number | ☐ Yes ☒ No<br>Comments:<br>These are organised by the trials units and study teams of the Portfolio studies, however MCRN has close links with these groups and regularly contributes to formal meetings associated with Portfolio studies | For example, investigator meetings, trainings specific to a given ongoing or planned trial. |
| 5.4<br>Training courses given over the last 2 years [M]<br>If yes, provide number | ☒ Yes ☐ No<br>Comments:<br>The MCRN is part of the NIHR Clinical Research Network, which operates a widescale training programme relating to all aspects of clinical research, and which is open to all investigators associated with MCRN Portfolio studies | 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<br>Training courses received over the last 2 years [M]<br>If yes, provide number | ☒ Yes ☐ No<br>Comments:<br>The MCRN is part of the NIHR Clinical Research Network, which operates a widescale training programme relating to all aspects of clinical research, and which is open to all investigators associated with MCRN Portfolio studies | 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). |

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| 5.6<br>Promotion of participation in clinical trials in countries with limited resources<br><br>Provide list of countries | ☐ Yes ☒ No<br>Comments: | 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.

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| 6.1<br><br>Involvement of patients, parents or their organisations in the protocol design | ☒ Yes ☐ No<br><br>Comments:<br><br>The MCRN Coordinating Centre and most of the MCRN Local Research Networks are committed to the involvement of children, parents and families in all aspects of network activity. The MCRN Children and Young Person's group regularly provides input to the design and delivery of MCRN Portfolio studies, and each of the MCRN Clinical Studies Groups has several parent members to ensure that the patient's perspective is considered in the development of new paediatric studies | Indicate if public stakeholders are /have been involved |
| 6.2<br>Involvement of patients, parents or their organisations in creating the protocol information package | ☒ Yes ☐ No<br>Comments:<br>The MCRN Children and Young Person's Group have produced a series of guidence documents to support the development of appropriate information leaflets for clinical research involving children. These are available via the MCRN website | Indicate if public stakeholders are /have been involved |
| 6.3<br>Involvement of patients, parents or their organisations in the prioritisation of needs for clinical trials in children | ☒ Yes ☐ No<br>Comments:<br>MCRN CSG regularly review their research priorities and the MCRN led a pan-Europe paediatric research prioritisation exercise as part of the ERANET PRIOMEDCHILD project. This included the involvement of parents and carers, and a number of parents presented their perspective on this prioritisation process at the international conference where the findings of the prioritisation exercise were presented and discussed | Indicate if public stakeholders are /have been involved |