

QUESTIONNAIRE I

FOR THE RECOGNITION OF REFERENCE CENTRES

DESCRIPTION OF THE REFERENCE CENTRE

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A. Instructions for completing the questionnaire

All questions must be answered, either in English, French or German. Incomplete questionnaires will be returned.

* = core criterion: A list of the core criteria is available in the Toolbox – Tool XI.

Your answers should be as precise as possible.

Please use continuous text without line breaks or bullet points, this helps with an efficient evaluation of the forms.

Please submit the questionnaire with the requested Annexes, inclusive an application letter from your institution signed by the medical director or directorate (*see template in the Toolbox – Tool VIII*) via e-mail (electronic format) and paper format to the following address:

kosek – Coordination of Rare Diseases Switzerland
c/o unimedsuisse
Haus der Akademien, Laupenstrasse 7
Postfach
3001 Bern
email info@kosekschweiz.ch

Please submit the complete application with all related documents by **31st December 2020**.



B. General information about the candidate centre

1. Name of the institution(s) responsible for the reference centre

(approximately 250 characters)

2. Name(s) of the medical director(s) or directorate(s) of your institution(s)

(app. 250 characters)

3. Name of the reference centre

(app. 250 characters)

4. What clinics/units constitute your candidate centre? Please list them

(app. 250 characters)

5. Address of the reference centre (including general email and telephone number)

(app. 250 characters)



6. Name and contact details of the coordinator/head of the reference centre (email address and telephone)

Explanatory note: the coordinator is responsible for the good functioning of the candidate centre and coordinates the clinical health care of patients.

(app. 250 characters)

7. For which diseases / (main) groups of diseases is your centre a candidate for recognition? Please list them.

Explanatory note: kosek works with the classification of rare diseases as used in the European Reference Networks (ERNs) and provided by Orphanet. The diseases are listed in the Excel sheet sent as a separate document (see Excel sheet ERN disease group). Please note that the document has different tabs.

Whenever possible, please list main groups of diseases. Please avoid listing diseases singularly (column G and onwards in the attached Excel sheet). If you need help with this specific question, please contact info@kosekschweiz.ch before answering.

ADD A DOCUMENT: Please list the diseases the reference centre is covering in a separate document (**Annex I.1**).

8. How are all other diseases / (main) groups of diseases in your given ERN classification provided for?

Explanatory note: in the previous question you listed the diseases / (main) groups of diseases you provide care for. In this question we would like to know how the whole disease group along the ERN classification is organised in Switzerland (i.e. to which colleague(s) or institutions do you refer patients suffering from a disease for which you do not have expertise?)

Please give a general overview using main groups of diseases whenever possible.

(app. 1000 characters)



9. What geographic/linguistic region is covered by your reference centre?

(app. 250 characters)

C. Clinical health care within your candidate centre

10. Please describe how your centre ensures multidisciplinary clinical health care for its patients with regard to

a. Diagnostics and therapy

(app. 1500 characters)

b. Follow-up of the patient

(app. 1500 characters)



11. Please describe the non-medical services for patients in your centre (i.e. care management, dietary consultation, psychosocial services, etc.) that are specific to the disease group your centre is candidate for.

(app. 3000 characters)

12. Does your centre offer other specific services or infrastructures to the patients in the disease group your centre is candidate for?

- Yes
- No

- a. If yes, please describe them.

(app. 3000 characters)



13. What forms of cooperation does your centre have at a regional / local level? Please describe the stakeholders and details of the cooperation.

Explanatory note: the goal of this question is to know whether and how the centre works with local family doctors, local specialists, local hospitals, etc.

(app. 3000 characters)

14. Please describe how multidisciplinary clinical health care is ensured at the INTERNATIONAL LEVEL for patients with regard to

a. Diagnostics and therapy

(app. 1500 characters)



b. Follow-up of the patient

(app. 1500 characters)

15. Can your candidate centre ensure multidisciplinary clinical health care for all diseases you are candidate for? * CORE CRITERION (including questions 15a and 15b)

- Yes
- No

a. If no, for which diseases is multidisciplinary clinical health care NOT provided?

(app. 500 characters)

b. Which institution(s) is your centre referring these patients to?

(app. 500 characters)



16. Does your centre have a rare disease board that is specifically for the disease group you are providing care for?

Explanatory note: the RD board does not have to be based in your institution. It can be organised within the national network / at a national or international level.

- Yes
 No

- a. If yes, please describe how it functions, its regular members/specialties, and its decision-making procedure.

(app. 1000 characters)

17. Is/are there (a) specific platform(s) within your institution that your centre uses to perform all necessary disease-related analyses for diagnosis and medical management? (several answers possible) * **CORE CRITERION**

Explanatory note: the word «platform» is to be understood as an infrastructure within your institution.

- Yes
 No

- a. If yes, please tick the platform(s) that is/are in place in your institution (several answers possible):

- Biomedical
 Genetic
 Pathological
 Laboratories
 Other (*please specify*):

(app. 250 characters)



18. What coding system does your centre use, to code the patients' diseases?

- Orphacode * **CORE CRITERION**
- ICD-10
- Human Phenotype Ontology (HPO)
- Other (*please specify*):

(app. 250 characters)

19. Does your centre follow existing disease-specific national or international guidelines and recommendations for the clinical health care of the patients?

- Yes
- No

a. If yes, please list them and specify if they are national or international.

(app. 500 characters)

20. Is your centre regularly involved in the preparation of guidelines or recommendation for the clinical health care of the patients?

- Yes
- No

a. If yes, please list them and specify if they are national or international.

(app. 500 characters)



21. What tools and/or processes did your centre develop / are you following in order to ensure transition between paediatrics and adult medicine? * **CORE CRITERION**

Explanatory note: You may add flowcharts, tables, figures or other helpful documents, in order to better explain your answer.

(app. 1000 characters)

ADD A DOCUMENT: if available add description of transition process (**Annex I.2**).

22. If the complexity of the disease makes it necessary, does your centre have the required infrastructure (i.e. day hospital) and staff (i.e. a case manager) at your disposal? * **CORE CRITERION** (including question 22a)

- Yes
- No

a. If yes, please describe the infrastructure and staff and how it is organised (including laboratories and genetics)

(app. 2000 characters)



23. Does your centre organise a 24/7 health care coverage for your patients with a rare disease?

- Yes
 No

a. If yes, please describe how it is organised (who is involved, procedure, etc.), including all available services that have to be in place in your centre (specialists, laboratories, products, non-medical staff, therapies, etc.)

Explanatory note: a 24/7 coverage can be organised within a network (or) at a national level. This question might be a core criterion for some diseases, but not for all, as not all diseases within a disease group require a 24/7 health care coverage.

(app. 250 characters)

24. What measures does your centre have in place for emergency units, in order to ensure appropriate health care for your rare disease patients in case of emergency (where patients are likely to be treated in an emergency unit)? Please describe them.

(app. 1000 characters)

ADD A DOCUMENT: please add a document, if you have a description of the emergency process or a tool available (**Annex I.3**).

25. During consultations with patients, do professionals in your centre share information about patient organisations with patients? (i.e. brochures, address of patient organisations/groups, etc.)?

- Yes
 No



26. Do patient organisations take part in the clinical health care within your candidate centre?

- Yes
- No

a. If yes, please describe how it is organised.

(app. 500 characters)

27. What kind of cooperation does your candidate centre pursue with patient organisations?
Please describe the cooperation and name the patient organisations involved.

(app. 1000 characters)

28. For newly diagnosed patients, does your centre organise exchange/counselling opportunities with other patients and/or patient organisations, if they are available?

- Yes
- No

***Explanatory note:** The diagnosis of a rare disease is often a great shock for the patients concerned, their parents and relatives. Interaction with people who have the same disease can help them cope with this shock. The point of view of those equally affected can alter the perspective of the newly diagnosed patient, facilitate the sharing of experience, and reduce stress.*



- a. If yes, please name the patient organisation(s) the exchange is organised with and describe the general procedure.

(app. 500 characters)

- b. If the centre does not organise any exchange opportunities with patients and/or patient organisations, please explain the reasons.

(app. 500 characters)

29. Does your centre measure patients' satisfaction with the services provided in your candidate centre?
- Yes
 - No

ADD A DOCUMENT: If yes, please provide the results of your most recent survey on patients' satisfaction (**Annex I.4**).



D. Communication and information

30. Does your centre have a structured communication system for the rare diseases you provide care for, in order to inform professionals inside and outside the hospital about the activities of your centre (i.e. family doctors, established specialists, etc. within your region)?

- Yes
- No

a. If yes, which one(s)? *(please tick the appropriate answer(s), several answers possible)*

- Internet and intranet
- Newsletter
- Special events
- Other *(please specify):*

(app. 250 characters)

b. If no, does your centre plan to establish a structured communication system for the rare diseases you provide care for?

- Yes
- No

c. If yes, please describe which one(s) and in what time-frame.

(app. 250 characters)

31. Does your centre have other structured communication systems for the rare diseases you provide care for, for care partners, or for the wider public, outside the hospital or the institution? * **CORE CRITERION** (including question 31a)

- Yes
- No

a. If yes, which one(s)? *(please tick the appropriate answer(s), several answers possible)*

- Internet/Webpage
- YouTube Channel
- Facebook /Twitter /Instagram specific page
- Newsletter
- Regular column in the mass media: which one(s)? *(please specify):*
- Seminars or public presentations or conferences
- Special events (e.g. rare disease day)
- Other *(please specify):*



(app. 250 characters)

32. What information measures has your centre set up in order to be found by patients? (*tick the corresponding answer(s), several answers are possible*)

- Orphanet website
- Website of your candidate centre
- National network website
- Helpline
- Established specialist(s)
- Specific events (i.e. public presentations, conferences, patient interaction opportunities, etc.)
- Other (*please specify*):

(app. 250 characters)

33. Does your centre take part in or organise events that promote dialogue and interaction between patients, patients' families, professionals?

Explanatory note: events can be meetings, camps, national days, assemblies of patient organisations to which professionals of your centre are invited to, etc.

- Yes
- No

a. If yes, please describe the events.

(app. 500 characters)



E. Continuing training of the candidate centre

34. Does your centre provide continuing training? * **CORE CRITERION**

- Yes
- No

35. At what level does it provide continuing training? (*please tick the corresponding answer – several answers possible*)

- local continuing training (i.e. continuing training for the hospital/institutional staff)
- continuing training at a national level, for the health care network?
- continuing training at an international level
- other continuing training offers? (debates, round tables, etc.) – please specify the type of continuing training:

(app. 250 characters)

ADD A DOCUMENT: Please list the **continuing training given by your candidate centre** during the past two years in a separate document. Please specify the target audience of the training (medical or non-medical staff) and at what level it took place (local/regional, national or international) (**Annex I.5**).

36. Does the staff in your centre receive regular continuing training? * **CORE CRITERION**

- Yes
- No

37. Please specify what kind of training the staff in your centre received (*tick the appropriate answer(s) – several answers possible*)

- local continuing training (i.e. continuing training for the hospital/institutional staff)
- continuing training provided by the national health care network
- continuing training provided at an international level
- other continuing training offers (debates, round tables, etc.) – please specify the type of continuing training.

(app. 250 characters)

ADD A DOCUMENT: Please list the **continuing training your staff has received** during the past two years in a separate document. Please indicate whether the training was provided at a local/regional, a national (i.e. within an existing network) or an international level (**Annex I.6**).



38. Are patient organisations involved in the organisation of the continuing training of your centre?

Yes

No

a. If yes, please describe how they are involved.

(app. 500 characters)

F. Research activities – research projects, registries, grants, etc.

ADD A DOCUMENT: please list in one document the peer-reviewed publications of your centre for the past five years, the current research projects and clinical trials of your centre, the main competitive and / or non-competitive grants and awards/recognitions received in the five last years. As a possible template see the Toolbox – Tool IX (**Annex I.7**).

39. Does your candidate centre publish on the specific rare diseases / (main) groups the centre provides for in peer-reviewed journals? * **CORE CRITERION**

Yes

No

40. Does your candidate centre have research projects for the specific rare diseases / (main) groups the centre provides for **AT PRESENT**?

Yes

No

41. Does your candidate centre take part in clinical trials **AT PRESENT**? * **CORE CRITERION**

Yes

No

42. Does your candidate centre receive competitive and/or non-competitive grants for research into the specific diseases/ (main) disease groups the centre provides for?

Yes

No



- a. During the past two years, has your candidate centre received any national or international award or recognition, for the specific rare diseases / (main) disease group it provides for?
- Yes
 - No

43. Does your candidate centre actively take part in disease specific registers by entering data?
- Yes
 - No

- a. In which disease-related registers does your centre enter data actively? Please provide a list.

(app. 1000 characters)

44. Does your candidate centre actively take part in the Swiss Rare Disease Registry by regularly entering data? * **CORE CRITERION**
- Yes
 - No



G. Coordination and administration

45. Please describe the structure of your candidate centre (organisation chart, names, functions and work percentage of the regular staff of the centre).

Explanatory note: You may add flowcharts, figures or tables if they help illustrate your answer.

(app. 1000 characters)

ADD A DOCUMENT: If available, please add a description of the structure of your candidate centre (organisation chart, functions and staff of the centre etc.) (**Annex I.8**).

46. What is included in the budget of your centre? (please list precisely what is covered by which clinic and any shortfalls)

(app. 1000 characters)



H. Documentation in Orphanet

47. Are your centre's activities registered in the Orphanet database?

- Yes
- No

a. If yes, please tick which one(s):

- Expert centres
- Research activities
- Clinical trials
- Diagnostic tests
- Registries
- Your centre's cooperation with patient organisations

48. Do you allow kosek to transfer your application to Orphanet in order to keep the Orphanet database updated? *(please tick the appropriate answer)*

- Yes
- No

Explanatory note: kosek works in collaboration with Orphanet Switzerland in order to simplify and to document the recognition procedure.

49. Does your reference centre wish to enter its scientific, clinical, registration and publication activities in the Orphanet database?

- Yes
- No

Explanatory note: The adding of information about these activities is voluntary. It allows Orphanet to include the information about your joint scientific, clinical and registration activities into its database for publication. Please use the separate template to describe your activities (see Toolbox: Tool IX). The Orphanet Switzerland team might need to contact the professional in charge in case they need a clarification for some of the data.

a. If yes, please list and describe the activities in a separate document.

ADD A DOCUMENT: Voluntary you can add a document enlisting the activities of your reference centre concerning research projects, clinical trials, registers and publications for registration in the Orphanet Database (**Annex I.9**, see template in the Toolbox – Tool IX).

50. Does your candidate centre follow certification/accreditation procedures, that are specific to the rare diseases/ (main) disease group(s) the centre provides for?

- Yes
- No

a. If yes, which one(s)?

(app. 250 characters)



I. Volume of activity

51. Total number of patients seen last year (absolute number)

(app. 250 characters)

52. Number of new cases last year (absolute number)

(app. 250 characters)

53. Number of patients from other cantons (absolute number)

(app. 250 characters)

54. Number of patients from other countries/abroad (absolute number)

(app. 250 characters)



J. General remarks

55. If you have a general comment or some elements to add to this questionnaire, you may do so in the comment section below:

Explanatory note: This field is optional.

(app. 1000 characters)



Checklist of the documents to enclose with the application

- | | |
|------------|--|
| Annex I.1 | List of the diseases the reference centre is covering
<i>(see Excel sheet of the ERN disease group)</i> |
| Annex I.2 | Description of transition process, if available |
| Annex I.3 | Description of the emergency process or a emergency tool, if existing |
| Annex I.4 | Results of last patient satisfaction survey with the services provided in your candidate centre, if available |
| Annex I.5 | List of the continuing training provided by your candidate centre during the past two years, including target audience of the training and level (local/regional, national or international) |
| Annex I.6 | List of the continuing training your staff has received during the past two years, including level of training (local/regional, national or international level). |
| Annex I.7 | List of the peer-reviewed publications of your centre for the past five years, the current research projects and clinical trials of your centre, the main competitive and/or non-competitive grants and awards/ recognitions received in the five last years |
| Annex I.8 | Description of the structure of your candidate centre (organisation chart, functions and staff of the centre etc), if available |
| Annex I.9 | Voluntary List of the activities of your reference centre concerning research projects, clinical trials, registers and publications for registration in the Orphanet Database
<i>(see template in the Toolbox – Tool IX)</i> |
| Annex I.10 | Application letter from your institution signed by the medical director or directorate
<i>(see templates in German and in French in the Toolbox – Tool VIII)</i>
<i>Please add your letter in one of these languages or in English).</i> |