Deliverable 5:

Registry analysis and Report

Questionnaire Results Report

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Questionnaire Results Report – results of analysis of PARENT online questionnaire to registry holders

Introduction

Overall view on purpose of questionnaire and its relation to Registry of Registries (RoR) pilot

The RoR questionnaire had the goal to provide information on existing patient registries for the state-of-the art analysis and input to create the pilot RoR.

Some other goals were set up later, during the workshops carried out in PARENT, in order to:

- Target specific fields of interest: dimensions.
- Identify the specific scope of each registry.
- Identify further dimensions and functionalities as quality preparation for RoR piloting.
- Serve as entry data for the RoR pilot.

During the workshops carried out with PARENT members and Associated Project Group (APG) partners, the questionnaire was divided in several dimensions, expressing different areas of future RoR functionalities:

- Respondent profile
- Registry entity
- Registry scope
- Registry use
- Data collection & products
- Data quality, linkage and sharing
- Level of cross-border activity
- Incentives to join RoR

Methodology, data collection and respondents

The construction of the questionnaire was a lengthy process which involved all the PARENT stakeholders and members, engaging them via a set of workshops, meetings and TCons in order to construct and agree on a final set of questions.

The full versions of the questionnaires in English and Spanish language are available in Annex 1 and Annex 2 of this deliverable.

The data collection process started on May 20th 2013 and the respondents were able to fill it in the English and Spanish languages. This analysis was performed on the data collected, with a cut-off point of July 10th 2013.

There was no piloting (apart from short technical piloting). In the data collection process several changes were performed to improve usability of the questionnaire. These changes were mostly structural and scale related.

In order to increase the amount of responses two reminders were sent to the registry holders: in English using the questionnaire email address (ror@hzjz.hr); and in Spanish through a specific email address; as well as via PARENT members in particular countries. Daily support and a 24hr response time to requests were provided by the data collection administration.

The first round of data was analysed using data received by July 10th 2013.

Respondents were recruited from the list of APGs as well as from the country members, who provided their national contacts for registries.

Altogether 131 respondents (98 English and 33 Spanish) filled in the questionnaire. There were some respondents who started but did not finish filling in the questionnaire due to various reasons. Some of them have let us know that they were not the type of registry of database to collect data from, or simply did not finish the questionnaire.

Data analysis

The results were analyzed in a descriptive manner, using Excel and SPSS software.

131 respondents (registries) answered the questionnaire; below is the table with country distribution. The '*sent questionnaire'* field represents the number of available contacts we have acquired from project partners, to which invitations were sent. Some of the contacts were no longer valid – presented in the '*wrong email*' category. These were taken out of the number of sent questionnaires, which brings us the number of valid contacts that we used as our sample. Percentage of responders thus relates to number of responders from a sample of valid contacts provided by partners.

As can be seen in the following table, Malta and Poland have a response rate greater than 100% which is explained by respective partners forwarding original email call to registries outside PARENT send list.

country	responders	sent questionnaire	wrong email	sample	%of respondents
Austria	5	53	6	47	11%
Croatia	9	16	2	14	64%
Cyprus	4	6	0	6	67%
Finland	11	20	3	17	65%
France	5	59	11	48	10%
Germany	2	7	1	6	33%
Greece	1	1	0	1	100%
Hungary	16	26	2	24	67%
Italy	3	6	2	4	75%
Ireland	1	2	1	1	100%
Latvia	11	14	2	12	92%
Malta	6	5	0	5	120%
Poland	8	6	1	5	160%
Portugal	2	60	6	54	4%
Romania	1	1	0	1	100%
Slovakia	1	11	1	10	10%
Slovenia	9	11	0	11	82%
Spain	35	163	27	136	26%
Sweden	2	5	2	3	67%
Total	**131**	**471**	**67**	**404**	**32%**

Willingness to participate in the RoR platform, barriers and motivations (Q40-42)

This area was defined through two questions:

Q40 Do you find it desirable that the EC and the Member States build a single IT-enabled platform that would assist users of registries data to identify more easily the relevant data/registry sources?

In this question **all the Spanish** respondents stated **yes**, and **84% of all respondents** also stated **yes** for a single EC IT-enabled platform.

Q41 Would you find it useful to have a European platform providing services for registries in your field of work?

In the above, **89% declared to find it useful to have an EU platform**.

A very important feedback in terms of what registry holders would like to see offered (also) through PARENT project is provided in table below. The question for registries was exploring what kind of services should be offered (Q42). The idea behind it was to try to identify services that are to be offered by the RoR (Registry of all registries) platform.

The most frequently stated first choices were *IT tools* and *Quality control systems*. Frequency of statements is shown below.

Services to be offered by EU platform	N	%
IT tools	81	21%
Legal advice	41	11%
Model documents	27	7%
Expert technical advice	28	7%
Quality control systems	78	20%
Networking	62	16%
Facilitated access to useful data sources	65	17%
Total	382	100%

Those who demonstrated *No* interest in the platform, gave the following explanations of their choice:

- *data provision stopped, protection of data privacy (IVF - in vitro fertilization registry)*
- *not allowed legally (HIV registry)*
- *already provided (cancer registry, registry of vaccination side effects, drug related mortality)*

Profile, entity, scope and use of registries (Q1-15)

In the following answers we can observe the profiles of the registries. The first one is related to the type of registry holder, where most registries claimed that it is a public health institution.

One must bear in mind that in case the total number of responses exceeds the sample number (N=131), this is due to the fact that this is a multiple answer question, where all the answers from multiple options are added up.

The following table represents types of registry holders (Q5) and their frequencies.

Type of registry holder Q5	N	%
Public health institution	74	46%
Public authority	43	27%
Health care provider	10	6%
Health professionals organization	17	11%
Academic institution	12	7%
Patient organization	3	2%
International/supranational	1	1%
Health insurance fund	1	1%
Total	161	100%

An additional table is provided with different combinations of registry holders and their frequencies.

Type of registry holder: combinations	N	%
Public health institution	56	43%
Public authority or government-appointed body	25	19%
Health professional's organisation	13	10%
Public health institution & public authority or government-appointed body	12	9%
Academic institution	7	5%
Healthcare provider	4	3%
Public authority or government-appointed body & health professionals' organization	2	2%
Public health institution & academic institution	2	2%
Academic institution & public authority or government-appointed body & health insurance fund	1	1%
Healthcare provider & academic institution	1	1%
Healthcare provider & health professionals' organization	1	1%
Healthcare provider & patient organization	1	1%
International/supranational body	1	1%
Patient organization	1	1%
Public health institution & healthcare provider	1	1%
Public health institution & healthcare provider & academic institution & public authority or government-appointed body & health professionals' organization	1	1%
Public health institution & health care provider & public authority or government-appointed body	1	1%
Public health institution & patient organization	1	1%
Total	**131**	**100%**

**Note: The frequency of 1% is rounded up (otherwise the total exceeds 100%)*

To have a detailed overview of types of registry holders per countries, the following table is displayed.

Type of registry holders Q5	Countries
Public health institution	at, hr, cy, fi, fr, hu, it, lv, mt, pl, ro, sk, si, es
Public authority	at, cy, fr, hu, lv, mt, pt, ro, es, ch
Academic institution	r, de, hu, pl, ro, efs, ch
Patient organization	fi, pt
Healthcare provider	hu, ie, pl, si, es
Health professionals organization	hu, pt, ro,
International/supranational body	Si

More than half of the registries were established by law, which in turn is related to the finding that most registries are national.

How was the registry established Q6	N	%
As part of a research project	27	17%
By law	69	45%
Autonomous initiatives	40	26%
Complying with internal requirements	19	12%
Total	155	100%

Initial and current registry funding reveal that, again, national authorities financed the setting up of registries, still remain their current source of financing, or have taken over funding, even if they were not founders.

Funding source Q7	Initial registry funding - set-up		Current registry funding	
	N	%	N	%
National government authority	58	36%	76	52%
No specific funding	27	17%	24	16%
Regional Authority	18	11%	18	12%
University/Research Institute	14	9%	1	1%
Foundation	12	8%	8	5%
EU commission agency	10	6%	3	2%
Hospital	10	6%	5	3%
Industry	9	6%	5	3%
Patient Association	2	1%	6	4%
Total	160*	100%	146	100%

** The difference in numbers of initial and current registry funding registries is due to missing answers.*

The governing board issue was interesting, since we were looking at how registries are being governed and whether governing boards have a specific structure and purpose. We found an equal split among registries with and without a governing board.

Registry having governing board Q8	N	%
No	65	50%
Yes	66	50%
Total	131	100%

The governing board structure in most cases is comprised of internal members.

Governing board structure Q9	N	%
Internal members	56	62%
External experts	20	22%
Patient representatives	6	7%
Funding representatives	7	8%
Industry representatives	2	2%
Total	91	100%

The governing board functions were in most cases to overlook database content, research and epidemiology. Coordination of all parties, data access, ethical and legal issues were also stated as board functions.

Governing board functions Q10	N	%
Database content, research, epidemiology	50	27%
Coordination all parties	32	17%
Data access	31	17%
Ethical and legal	31	17%
Administration and financial	22	12%
Communication funding, patients, HC	21	11%
Total	187	100%

As mentioned previously, most of the registries in our sample are national.

Registry geo coverage Q11	N	%
National	105	77%
Regional	25	18%
International	3	2%
Organization specific	2	1%

EU	2	1%
Total	137*	100%

**Note that there are combined answers in the sample which explain the total exceeding the sample number.*

When asked on entry criteria, we have gained a set of additional criteria entered in the free text field. As we have divided the types of registries in three ways, the respondents were offered to select their registry type and write in the type of their registry.

Registry type Q13	**N**	**%**
Condition based	100	76%
Services based	28	21%
Product based	3	2%
Total	131	100%

The types of condition-based registries were various, such as: cancer, birth and death registries, injuries, multiple sclerosis, mental disorders, congenital anomalies, tuberculosis, CVDs etc. Medical devices and pharmaceutical products were the objects of product-based registries, whereas service-based registries stated mostly hospital and outpatient discharge registries as well as vaccinations and obstetrics.

The primary observational unit was - as expected - mostly the person.

Primary observational unit Q14	**N**	**%**
Person	79	60%
Event	41	31%
Product	5	4%
Service	6	5%
Total	131	100%

It might seem unusual that a couple of registries stated the service as a primary observational unit. When data are looked at more closely, some additional registries that are service-based did not state service as their primary observational unit.

As we have offered to respondents two main categories of registry use, the largest share of respondents selected statistics as the primary use. Other primary registry use types were: IVF treatment costs, payment to healthcare providers and others. Less frequent primary registry use types were: access to therapy for chronic viral hepatitis, compensation of IVF treatment costs, payment to health care providers, research and others.

Primary registry use Q15	**N**	**%**
Statistics	82	64%
Surveillance	34	27%
Other	12	9%

Total	128*	100%

**Note: missing answers (variables) account for the remaining responders.*

Other secondary registry use types were the following: improvement of stroke care monitoring, monitoring registries, research studies, data for selected projects, calculations of general practitioner capitation fee, use of biologics, epidemiology and similar. Less frequent secondary registry use types were also interesting: creating strategy for TB (tuberculosis), improvement of stroke care system, prevention programme evaluation and others.

Data: collection, quality, linkage, sharing

In our sample there were four registries dated in 2013. 47% of registries still use paper for data collection(paper based questionnaires and paper based health care records); 43% already rely on electronic means (online questionnaires, electronic health care records and laboratory results).

Sources of data Q17	N	%
Paper based questionnaires	67	22%
Electronic health care records	56	18%
Online questionnaires	53	17%
Paper based health records	44	14%
Paper based laboratory results	34	11%
Electronic laboratory results	26	8%
Directly from clinical examinations	17	5%
Interviews	14	5%
Total	311	100%

Combinations of different practices per registry varied in all forms (online and electronic health records, all paper based forms, online and all other forms) and in countries.

As for data providers (Q18), clinical units and laboratories were the most frequent data providers.

Data quality indicators (Q19) were stated in most registries, for example: patient IDs, validation of random samples, proportion of missing cases, logical controls, or indicators developed specifically for the registry.

Representative sample for the particular population was stated in 61% of cases, again related to national scope of registries. The explanation on why the sample is not representative for certain (49%) of registries falls out of scope of this questionnaire and analysis.

Registry having representative sample Q20	N	%
Yes	80	61%
No	51	39%
Total	131	100%

When coming to standardized data exchange format, we found that most of registries do not have it.

Registry having standardized data exchange format Q21	N	%
Yes	29	22%
No	102	78%
Total	131	100%

Registries having standardized data exchange noted the following formats: Excel, XML, standardized files upload and electronic health care records, csv forms, and other data exchange specific forms.

The majority of responding registries (n=102 78%) use a standard unique identifier for data subjects, which is most often a national (citizen) number (see below tables for distributions across various categories of identifiers).

Does the registry contain standard unique identifier of data subjects? Q22	N	%
Yes	103	79%
No	28	21%
Total	131	100%

If yes, what kind of identifier?	N	%
National (citizen) number	43	42%
Social security code	16	16%
Tax number	1	1%
Yes (no specification)	4	4%
Other	39	38%
Total	103	100%

Interest in linking data with other data sources was expressed, and the highest interest to link with was with hospital health care providers and cause of death registries. All countries had at least one registry with interest in linking data. Also, half of the registries that currently do not link data expressed interest in linking data with other data sources.

Interest in linking data with other data sources Q25	N	%
Yes	79	60%
No	52	40%
Total	131	100%

Answers on current linkage of registry data was equally distributed between having and not having linkage to other data sources. The data sources most commonly linked to are shown in the following table.

If yes, source of data for linkage (all)	N	%
Cause of death registry	41	35%
Population registry	31	27%
Hospital/healthcare provider databases	23	20%
Additional source	21	18%
Total	116	100%

Regarding additional approvals for data sharing (Q27), the ethical committee and the ministry of health were predominant; 32% of the registries have published procedures for data access requests coming from external parties. Mostly there are no specific fees involved.

Primary reason of data requests reported was: building a database, international legislative, vaccine safety, international comparison, and statistics reporting on EU level.

Cross-border activity (Q31-39)

We asked the respondents on the yearly number of cross-border requests for data access. Most of the registries stated that they did not have such requests; thus there seems to be almost no cross-border exchange of registry data in the EU.

Respondents who stated that they had data requests (42% of registries) defined a frequency of data requests of around 2-5 requests per year. The countries reported to request data were: EU, Italy, France, UK, Germany, Spain; also mentioned were Portugal, Austria, the Netherlands and countries of the former Yugoslavia region.

The reported institutions requesting data were: Eurostat, WHO, OECD, various research projects or related similar registries (APGs). Almost none of the requests involved identifiable micro data. There were three registries providing micro data: a registry of State Health Care Users; a registry of Creutzfeldt-Jakob disease and related disorders and one Congenital Anomalies Registry. As for the proportion of approved international applications, there is extensive variation but predominantly there has either been no such requests or they were rejected.

% of approved applications for data Q37	N	%
0%	45	35%
100%	18	14%
90%	10	8%
80%	6	5%
70%	3	2%
60%	0	0%
50%	4	3%
40%	0	0%
30%	1	1%
20%	1	1%
10%	5	4%
No Such Applications	34	27%
Total	127*	100%

**4 missing variables (answers)*

The time required to process applications for access to registry data varies widely as displayed in the following table.

No. of weeks needed for approval of data request Q38	Total
0	21
1	15
2	12
2-3	1
3	9
4	14
5	2
6	4
8	3
10	1
12	4
26	3
No answer	42
TOTAL	**131**

Willingness to participate in a EU IT enabled platform (Q40) was expressed by84% of respondents; the most frequent areas were IT tools and quality control.

Areas of participation in RoR Q42	N	%
IT tools	80	21%
Quality control	76	20%
Facilitated access to useful data sources	65	17%

Networking	61	16%
Legal advice	40	11%
Expert technical advice	28	7%
Model documents	26	7%
Total	376	100%

Respondents who stated that they were not interested in participation claimed the following reasons (21 registries): already have a similar platform (a national antibiotic resistance surveillance registry, a bone marrow international registry); protection of data privacy (an IVF-Register); the law does not allow (an HIV/AIDS registry).

Finally, a list of interesting suggestions and remarks from respondents:

"I suggest that we build any further registries on the basis of the already functioning international registries"

"The most important objective for us is to form suitable (cross-border available) CEN 13606 based archetypes to correctly describe EHR of clinical events"

"I think all cancer registries need to have the same type of template where we insert all the information required regarding the cases but unfortunately we need more human resources as we are only three people working on the cancer register."

"Registries must result from the good register of the daily practice activity without duplicating the team work."

"Friendly dedicated softwares incorporating specific guidelines can help team, standardize care and build databases for investigation and regulation (quality/financial...)."

Conclusions

During less than four months of data collection we have had an average 32% response rate. Due to controlled and limited extent of promotion of the questionnaire (mainly targeting national registries), this rate may be considered satisfying. The results also include data from the second round of questionnaire invitations, where invitations were sent to additionally identified registries one month before closing the questionnaire submissions and no additional reminders were sent. Most of the registry identification process and invitations went through parent country members, internal project communication, and to some extent DG SANCO.

Most of the registries involved in data collection were national registries, established by law and financed by national authorities. 43% of all the registries used online electronic questionnaires (health care and laboratory direct input).

One of the important findings is that cross-border data sharing or exchange is happening only to a very limited extent. Cross-border cooperation between registries nevertheless exists in certain areas.

Also, most registries are lacking standards for data exchange and an underlying interoperable IT platform.

An important message to PARENT and the registry policy makers is that there is registries' willingness to use/participate in an EU IT-enabled platform – this was expressed by 84% of respondents. This result gives support to PARENT plan to develop RoR and other tools and services in what we call the PARENT Framework.

As one registry stated, drivers can be found in "friendly software" that can "*help the team, standardize care and build databases for investigation and regulation (quality/financial)".*

Limitations of instruments and data collection results

The questionnaire was created using a participative approach (multiple stakeholder input) in a limited time span and thus its robustness could not be fully tested in advance. As a result we have mostly been performing only descriptive analysis of the results.

The limitations of the data collection process are at least twofold: one of them is the usability and availability of the online questionnaire (depending on the speed of internet connection and the overall usability and performance of the tool used to provide the questionnaire); the other one is related to respondents, as in some cases there was missing communication between partners providing contact of registry holders and the respective registry holders who were not fully informed why they were selected for this data collection.

Recommendations for further iterations of questionnaire (new APGs and new registries)

Based on this data collection experience, we strongly encourage that all of the respondents are better pre-informed, both on a local country level and on a project level.

Action steps based on results

The first action step was mapping the responses to the future RoR and PARENT Framework functionalities.

The second step is toward following iterations of the data collected, preparing area specific questionnaires (such as one for arthroplasty group) and performing additional specific surveys, such as a device registry adapted survey to gain more detailed insight into areas of greater interest or importance.

Moreover, evidence gathered from this questionnaire should be further explored through quantitative analysis and contacting (interviewing) registry holders directly.

Dear Patient Registry manager,

Please read on - this survey is of importance both to you and your registry as well as public health policy in the EU.

Based on your national representative in PARENT Joint Action we believe you are the key person to provide insight into your registry. If this is not correct, we kindly ask you to indicate via email (ror@hzjz.hr) the correct person to talk to.

Background of the project and role of the questionnaire

PARENT Joint Action* (www.patientregistries.eu)** *is a key joint activity by EC and Member States aimed at improving cross-border use of data from patient registries. PARENT aims among others to set up* ***Guidelines and Recommendations to Member States for setting up and managing interoperable patient registries*. It also aims to pilot a* ***Registry of Registries*** *to allow for search and comparison of existing patient registries.*

Building upon work already performed by ***EPIRARE, European Society of Cardiology, AHRQ*** *and others,* ***this survey*** *will provide information on existing patient registries for state-of-the-art analysis and input to create the pilot Registry of Registries (RoR).*

We kindly ask you to reserve up to 20 minutes for completing the questionnaire. You can save a partial response and complete it later (in case you need to consult someone).

You can also preview/print a PDF version of the online questionnaire – (right top corner of the screen) to help you prepare your response. Please fill the on-line questionnaire only and don't send back the filled pdf file. Please fill in the on-line questionnaire within [date]. Questions marked with an asterisk (*) require an answer.

In case you cannot provide all answers, please provide here the details of the person that can provide additional answers and we will notify them. Your partial response will be saved for the additional person to finalize.

Respondent profile

In this section you are asked to provide information to help us build the profile of respondents, such as background and affiliation. Please be aware that in accordance with personal data regulation, all personal data collected through this survey will be kept according to legal security requirements and ultimately deleted.

1. Please provide your contact details:

Name and Surname
Name of the Registry (in English language; in local language)
City
Region
Country
Email
Phone number (including country code) (+nnn)

2. When was the registry started (first case collected)?

_____ (if not sure, round to closest year)

3. Is your registry currently active (still collecting data)?

a) yes
b) no– if no, when did data collection stop?

4. Please indicate:

4.1. Total number of cases (approximate number or not available)

_____

4.2. Number of active cases (approximate number or not available)

_____

4.3. Average number of new cases per year (approximate number or not available)

_____

Registry entity

5. Please indicate the type of registry holder?

a) Public health institution
b) Healthcare provider
c) Academic institution
d) Public authority or government-appointed body
e) Health professionals' organisation
f) International/supranational body
g) Health insurance Fund
h) Industry (pharma, medical device etc.)
i) Patient organisation
j) Other – please specify

6. How has your registry been established?

a) By law (please provide here the reference to the specific law(s)
b) To comply with international requirements
c) As part of a research project
d) Following autonomous initiatives (clinicians, patient driven initiatives etc.)
e) Other (please specify _____)

7. Please indicate the initial funding source and present funding source

	Registry set up - funding by	Registry today - funding body
No specific funding source		
Regional government authority		
National government authority		
University/Research Institute		
Hospital		
Patient Association		
Foundation		
Industry		
EU commission/agency		
Not available information		
Other - please specify: _____		

8. Does your registry have a governing board?

Yes/No

9. If yes, how is it composed?

- Internal members (from the organisation that is the registry holder)
- Patient representatives
- External experts (from outside of the organisation that is the registry holder)
- Industry representatives
- Representative of source of funding
- Other - please specify _____

10. IF YES, What are the main functions of the governing board? (select all that apply)

- Financial and administrative issues
- Ethical and legal issues
- Database content, research objectives, epidemiology, biostatistics, etc.
- Communication with the funding source, health care providers, patients
- Data access and use by internal and external researchers
- Coordination of all parties involved in the registry
- Other - please specify

Registry scope

11. What is the registry's geographical coverage?

a) International
b) EU
c) National
d) Regional
e) Organisation specific
f) Other – please specify _____

12. Please describe what are the entry criteria for patients to enter the registry

(for example adults aged above 45 with a clinically confirmed diagnosis of Diabetes Mellitus Type II living in Croatia)

Criterion 1: _____ (free text)
Criterion 2: _____
Criterion 3: _____
Add more criteria

13. What is the registry type?

a) condition based
- diabetes
- circulatory system diseases
- cancer
- rare diseases
- other - please specify

b) product based:
- Medical device
- Pharmaceutical product
- Other - please specify

c) services based:

- Hospital discharge
- Outpatient discharge
- Vaccination/immunization
- Other – please specify.

14. What is the primary observational unit?

a) a person
b) an event (if yes please specify type of event) _____
c) a hospital discharge or any other service
d) product (medical device, pharmaceutical product)
e) Other – please specify.

Registry use

15. Please mark your answers in columns

	Primary purpose of registry - one answer only	**other registry purposes - please select all that apply**
Statistics (different reports to national and international organisations, indicators, etc),		
Surveillance		
Other – please specify?		

Data collection & products

16. From which year did the registry become available electronically? (in case you have subsequently transferred the paper collected data into an electronic format)?

_____

17. From which of the following sources do you obtain data? Please select all that apply:

a) Paper based questionnaires or structured reports
b) Online/electronic questionnaires or structured reports
c) Electronic health records, electronic hospital information systems and other electronic sources of clinical data
d) Paper based health records (practice or hospital based)
e) Directly from clinical examinations (without health record as intermediary)
f) Paper based laboratory results
g) Electronic laboratory results
h) Interviews
i) Other – please specify

18. Who is your major data provider?

j) Clinical units (within hospitals, practices, outpatient clinics etc.)
k) Laboratories/central services (biochemistry, pathological services, genetic, Rx, etc)
l) Discharge registries
m) Patients and families
n) Patients' groups (associations/federations)
o) Disability registries
p) Centres of expertise
q) Birth registries
r) Cause of death registries
s) Insurance funds (public and private)
t) Other registries

u) Other (please specify)

Data quality

19. Please briefly list the quality indicators monitored in your registry:

____

20. Does your registry include a representative sample for a particular population?

a) yes (if yes please specify which (i.e. country wide population of diabetes mellitus II patients; regional population of disease X)
b) no

21. Does your registry use a standardized data exchange format such as HL7, for export purposes?

If you use any other standardized data exchange format, please specify?

Data linkage and sharing

This section should provide information about the 'shareability' of the data-set, in terms of purposes, approvals, and consents.

22. Does your registry contain any standard unique identifier on data subjects?

a) yes Please specify:

National(Citizen) Number

Social security code

Tax number

Other – please specify _____

b) no

23. Is the data from your registry routinely linked to data from other sources / registries?

a) yes
b) no

24. If yes, which ones (e.g. other registries, hospital, health care provider databases etc.) and for what purpose(s)?

Source of data for linkage with your registry	**Purpose of linking** - specify purpose
Hospital/healthcare provider databases	
Population registry	
Cause of death registry	
Please enter additional source if you use it	

Please enter additional source if you use it	
Add source	

25. Would you be interested to link your data with other data sources?

a) yes
b) no

26. If yes, which sources and for what purpose

Source of data for linkage with your registry	**Purpose of linking**
hospital/healthcare provider databases	
population registry	
cause of death registry	
Add source	Specify purpose

27. What additional approvals are required for you sharing the registry data with external parties (i.e. research projects, stakeholders, the Ministry, general public etc.)?

_____

28. Please provide the details of the contact person dealing with enquiries related to access to your registry's data

Name and surname, email, contact phone

29. Let's assume an external party wishes to access data from your registry. Is there a published procedure regarding access to the data?

a) yes – please provide the link _____
b) no

30. Are there specific fees involved in providing access to data from your registry? Please describe briefly.

___

Level of cross-border activity:

31. How many requests for data access originating from another country do you receive per year?

32. From which country(ies) do you receive requests most frequently? ____

33. From what type of institutions does the request usually originate?

34. To which clinical area(s) do most requests pertain?

35. What is the most common reason a foreign institution gives when requesting access to your registry data?

- There are no such requests
- The primary reason is ___

36. Do requests for data involve access to identifiable (micro) data?

37. What percent of received international applications for data access do you approve?

38. How long does it take (in weeks) for a decision to be made on an application (rejected or approved)?

39. Please describe how do you (physically/electronically) provide data (or data access) to applicants from outside your country of operations?

Incentives to join RoR

40. Do you find it desirable that the European Commission and Member States build a single IT-enabled platform that would assist users of registry data identify more easily the relevant data/registry sources?

a) yes
b) no

41. Would you find it useful to have a European platform providing services for registries in your field of work?

a) yes
b) no

42. If yes: Please indicate which of the services below should be offered by a EU platform for registries (select only 3 most important):

a) IT tools (e.g. software for database management, data exchange, security and privacy etc.)
b) Legal advice
c) Model documents (e.g. Informed consent form)
d) Expert technical advice
e) Quality control systems, quality expert advice, etc.
f) Networking among registries and stakeholders
g) Facilitated access to useful data sources
h) Other – pls specify

If no, why?

i) Registry is no longer active.
j) Data providers stopped providing data (for whatever reason).
k) Other – please specify

43. Please describe or suggest keywords that best describe your registry (keywords that could be used for indexing in the PARENT Registry of Registries (PARENT RoR).

44. Any additional information, feedback, ideas etc.

Dear registry holder, you have reached the end of the questionnaire. If there are questions you cannot answer yourself, please save the survey and finish it after consulting with your colleagues. If you find someone else more appropriate to finish the survey, please provide contact details here and we will send the current version to him/her. PARENT team is very thankful for your time in completing this important survey!

SAVE / SUBMIT

Estimado titular del Registro de pacientes:

Por favor, lea con atención. Le rogamos que rellene el cuestionario que encontrará a continuación, cuyos resultados serán de gran importancia para usted, para su registro y para las futuras políticas de salud pública en la UE.

En opinión de su representante nacional en el proyecto *PARENT Joint Action creemos que usted es la persona indicada para proporcionarnos una idea sobre su registro. Si esto no es correcto, le rogamos que nos lo haga saber y que nos indique además, por correo electrónico (ror@hzjz.hr), la persona indicada para tal fin, con el objeto de que podamos contactar con dicha persona.

Antecedentes del proyecto y papel que desempeña el cuestionario

** PARENT Joint Acción (www.patientregistries.eu) es una actividad clave que realizan la Comisión Europea y algunos Estados Miembros de forma conjunta, con el objetivo de mejorar el uso transfronterizo de los datos almacenados en los registros de pacientes. PARENT pretende, entre otros objetivos, establecer futuras directrices y recomendaciones, dirigidas a los Estados miembros, destinadas a la creación y gestión de registros de pacientes de forma que resulten interoperables entre sí. Asimismo, su objetivo principal es la creación de un Registro General de Registros que permita la búsqueda y comparación de los registros de pacientes ya existentes.*

*Basado en el trabajo realizado por iniciativas como EPIRARE, European Society of Cardiology, la AHRQ (*Agency for Healthcare Research and Quality) *y otros, este estudio nos suministrará información sobre los actuales registros de pacientes con la que podremos realizar un análisis de su estado actual y que, además, proporcionará datos para la creación del Registro piloto de Registros (RoR).*

Le rogamos que rellene el cuestionario que encontrará a continuación, lo cual le llevará no más de 30 minutos de su tiempo. A medida que vaya respondiendo, podrá ir guardando sus respuestas de forma parcial y terminar de completarlo en otro momento si necesita realizar alguna consulta con otra persona.

También podrá ver o imprimir una versión en PDF del cuestionario en línea - (esquina superior derecha de la pantalla) que puede resultarle útil para preparar

sus respuestas. Le rogamos que rellene solo el cuestionario online, no envíe el documento en pdf y que lo haga en la fecha indicada.

Las preguntas marcadas con un asterisco (*) requieren ser respondidas obligatoriamente.

En caso de que usted no pueda facilitarnos todas las respuestas, le rogamos que nos indique los datos de contacto de la persona que pueda aportarnos el resto de las respuestas, para que podamos ponernos en contacto con dicha persona. La parte del cuestionario que haya sido respondida por usted quedará guardada con el fin de que la otra persona solo tenga que finalizarlo.

Perfil del encuestado

En esta sección se le pide que proporcione información que nos ayuden a construir el perfil de los encuestados con datos como: antecedentes y afiliación. Le rogamos que tenga en cuenta que, de conformidad con el Reglamento 45/2001 del Parlamento Europeo, todos los datos personales, recogidos a través de este cuestionario, se guardarán en conformidad con el reglamento legal de seguridad y protección de datos y se eliminarán en última instancia.

1. Por favor, proporcione sus datos de contacto:

Nombre y Apellidos _____

Nombre del registro (ya sea en Inglés o en su idioma local) _____

Ciudad _____

Región _____

País _____

Email _____

Número de teléfono (incluyendo código de país) (+ nnn) _____

2. ¿En qué año se inició el registro (primer caso recogido)?

Año: _____ (En caso de duda, indique el año que más se aproxime)

3. ¿El Registro continúa activo en la actualidad (se siguen recopilando datos)?

a) SI

b) NO. Especifique el año en que se detuvo la recopilación de datos: _____

4. Por favor, indique:

4.1. Número total de casos registrados (número aproximado / no disponible)

_____

4.2. Número de casos activos (número aproximado / no disponible)

_____

4.3. Promedio del número de casos nuevos por año (número aproximado / no disponible) _____

Entidad Titular del Registro

5. Por favor, indique el propietario del registro

Respuesta múltiple

a) Institución de salud pública

b) Proveedor de asistencia sanitaria

c) Institución académica

d) Autoridad pública u organismo designado por el gobierno

e) Organización de profesionales sanitarios

f) Organismo internacional / supranacional

g) Sistemas de aseguramiento (público o privado)

h) Industria (farmacéutica, dispositivos médicos, etc.)

i) Organización de pacientes

j) Otros: _____

6. ¿Cómo se estableció su registro?

Respuesta múltiple

a) Por ley (indique aquí la referencia a las leyes específicas)

b) Para cumplir con requisitos internacionales

c) Como parte de un proyecto de investigación

d) Por iniciativa propia (médicos, iniciativas impulsadas por pacientes, etc.)

e) Otros: _____

7. Indique la fuente de financiación inicial y la fuente de financiación actual

	Financiación inicial del Registro	Financiación actual del Registro
Sin fuente de financiación específica		
Autoridad regional		
Autoridad nacional		
Universidad / instituto de investigación		
Hospital		
Asociación de pacientes		

Fundación		
Industria		
Comisión EU /agencia		
Información no disponible		

Otros: _____

8. ¿Tiene su registro un órgano de gobierno o comité de seguimiento y control?

a) SI

b) NO

9. En caso afirmativo, ¿cómo se compone?

- Miembros internos (de la organización titular del registro)
- Representantes de pacientes
- Expertos externos (ajenos a la organización titular del registro)
- Representantes de industrias
- Representantes de las fuentes de financiación
- Otros: _____

10. En caso afirmativo, ¿cuáles son las principales funciones de la junta de gobierno? (Seleccione todas las que se puedan aplicar)

Respuesta múltiple

- Cuestiones financieras y administrativas
- Aspectos éticos y legales
- Contenidos de la base de datos, objetivos de la investigación, epidemiología, bioestadística, etc.

- Comunicación con la fuente de financiación, proveedores de salud, pacientes.
- Acceso a los datos y a su uso por investigadores internos y externos.
- Coordinación de todas las partes involucradas en el registro.
- Otros: _____

Ámbito del Registro

11. ¿Cuál es la cobertura geográfica del registro?

a) Internacional

b) Europea

c) Nacional

d) Regional

e) Organización particular

f) Otros: _____

12. Describa los criterios de inclusión de pacientes en el registro:

Por ejemplo: adultos mayores de 45 años, con diagnóstico clínico confirmado de Diabetes Mellitus tipo II, residentes en España (Texto libre)

Criterio 1: _____

Criterio 2: _____

Criterio 3: _____

Cualquier otro criterio: _____

13. ¿De qué tipo es el registro?

a) Basado en una condición de salud

- Diabetes
- Cardiovascular
- Cáncer

- Enfermedades Raras
- Otros: _____

b) Basado en productos sanitarios:

- Dispositivo médico
- Producto Farmacéutico
- Otros: _____

c) Basado en servicios sanitarios:

- Alta hospitalaria
- Alta de paciente externo
- Vacunación
- Otros: _____

d) Otros: _____

14. ¿Cuál es la <u>principal</u> unidad de observación?

a) Una persona

b) Un evento ¿de qué tipo?_____

c) Un alta hospitalaria o cualquier otro servicio

d) Un producto (dispositivo médico, producto farmacéutico)

e) Otros: _____

Usos del Registro

15. Escriba su respuesta en columnas

	Propósito principal del Registro (respuesta única)	**Otros propósitos del Registro (respuesta múltiple)**
Estadísticas (informes dirigidos a las organizaciones nacionales e internacionales,		

indicadores, etc.)		
Vigilancia		
Otro		

Recolección de datos y productos

16. ¿Desde qué fecha (año) se encuentran disponibles los datos en formato electrónico? (En caso de que los datos recogidos en papel se hubieran transferido, posteriormente, a formato electrónico) _____

17. ¿De cuál de las siguientes fuentes se obtienen los datos?

Respuesta múltiple

a) Cuestionarios o informes estructurados en papel

b) Cuestionarios o informes estructurados electrónicos

c) Registros de salud electrónicos, sistemas electrónicos de información de los hospitales y otras fuentes electrónicas de datos clínicos

d) Registros de datos sanitarios en papel (hospital o basados en consultas)

e) Directamente de los exámenes clínicos (sin registro de datos sanitarios intermediario)

f) Resultados de laboratorio en papel

g) Resultados de laboratorio en formato electrónico

h) Entrevistas

i) Otros: _____

18. ¿Quién es su principal proveedor de datos?

Respuesta múltiple

a) Unidades clínicas (en hospitales, consultas, ambulatorios, etc.)

b) Laboratorios / servicios centrales (bioquímica, anatomía patológica, genética, radiología, etc.)

c) Registros de altas hospitalarias

d) Pacientes y sus familias

e) Grupos de pacientes (asociaciones / federaciones)

f) Registros de discapacitados

g) Centros especializados

h) Registros de nacimientos

i) Registros de causas de defunción

j) Sistemas de aseguramiento (públicos y privados)

k) Otros registros: _____

l) Otros: _____

Calidad de los Datos

19. Enumere brevemente los indicadores de calidad controlados en su registro

_____

20. ¿Su registro incluye una muestra representativa de una población en particular?

a) SÍ. Especifique cual: (por ejemplo: población de pacientes con diabetes Mellitus II en el país, población regional con enfermedad X)_____

b) NO

21. ¿Su registro utiliza un formato de intercambio de datos estandarizado, como el HL7?

a) SI

b) NO

En caso de que utilicen cualquier otro formato normalizado de intercambio de datos, por favor especifique:

_____

Vinculación e Intercambio de Datos

Esta sección debe proporcionar información acerca de la capacidad para compartir que posee el conjunto de datos, en términos de propósitos, aprobaciones y consentimientos.

22. ¿Su registro contiene algún identificador estándar para datos de sujetos en particular?

a) SI

- Número de identificación nacional
- Código de Seguridad Social
- Número de identificación fiscal
- Número de la tarjeta del sistema nacional o regional de salud
- Otros: _____

b) NO

23. ¿Los datos de su registro se vinculan de forma rutinaria a los datos procedentes de otras fuentes o registros?

a) SI

b) NO

27. En caso afirmativo ¿qué otros registros (por ejemplo: hospitales, bases de datos de proveedores de asistencia sanitaria, etc.) y con qué propósito / s?

Fuente de los datos vinculados a su	**Propósito de la vinculación**

registro	
Bases de datos de hospitales o proveedores de atención sanitaria	
Registro de población	
Registro de causas de mortalidad	
Otras fuentes:	

25. ¿Le interesaría vincular sus datos con otras fuentes?

a) SÍ

b) NO

26. En caso afirmativo ¿qué fuentes y con qué propósitos?

Fuente de los datos vinculados a su registro	**Propósito de la vinculación:**
Bases de datos de hospitales o proveedores de atención sanitaria	
Registro de población	
Registro de causas de mortalidad	
Otras Fuentes:	

27. ¿Qué aprobaciones adicionales serían necesarias para que compartiera los datos de su registro con alguien ajeno a él (por ejemplo: proyectos de investigación, partes interesadas, Ministerio, público en general, etc.)?

_____

28. Por favor proporcione los datos de contacto de la persona encargada de responder a las consultas relacionadas con el acceso a los datos de su Registro:

Nombre y apellido, correo electrónico, teléfono de contacto_____

29. Supongamos que alguien ajeno desea tener acceso a los datos de su registro. ¿Se encuentra publicado algún procedimiento a seguir, en cuanto al acceso de datos?

a) SÍ. Por favor, proporcione el enlace_____

b) NO

30. ¿Existen tarifas específicas para el acceso a los datos de su registro? Por favor describa brevemente: _____

Nivel de Actividad Transfronteriza

31. ¿Cuántas solicitudes de acceso a datos, reciben ustedes al año, provenientes de otros países? _____

Si reciben solicitudes de este tipo, por favor responda a las siguientes preguntas:

32. ¿De qué país o países recibe usted solicitudes con mayor frecuencia?

_____

33. ¿De qué tipo de instituciones provienen por lo general esas peticiones?

_____

34. ¿A qué área clínica se refieren la mayoría de las solicitudes?

_____

35. ¿Cuál es el motivo más habitual que una institución extranjera les da cuando solicitan acceso a los datos de su registro?

- No recibimos ese tipo de solicitudes
- El motivo principal es _____

36. ¿Están relacionadas dichas solicitudes con el acceso a (micro) datos identificables?

a) SI

b) NO

37. ¿Qué porcentaje de las solicitudes internacionales de acceso a datos, que reciben, aprueban ustedes? _____

38. ¿Cuánto tiempo tardan (en semanas) en tomar una decisión sobre una solicitud (ya sea rechazada o aprobada)? _____

39. Por favor describa de qué forma (física / electrónica) ofrecen ustedes los datos (o el acceso) a los solicitantes de fuera del país en el que operan?

_____

Motivaciones para unirse al Registro de Registros

40. ¿Le parece conveniente que la CE y los Estados miembros creen una sola plataforma informática, habilitada con la finalidad de que pueda ser utilizada por los usuarios, como ayuda en la búsqueda de datos de registros con el propósito de que los datos relevantes y las fuentes del registro resulten más fáciles de identificar?

a) SÍ

b) NO

41. ¿Le parece útil disponer de una plataforma europea que preste servicios en su campo de trabajo?

a) SI

b) NO

42. En caso afirmativo, le rogamos que indique cuáles de los siguientes servicios deberían ser ofrecidos por una plataforma europea dirigida a registros (seleccione sólo los 3 más importantes):

a) Herramientas informáticas (por ejemplo: software para la gestión de bases de datos, intercambio de datos, seguridad y privacidad, etc.)

b) Asesoramiento jurídico

c) Documentos modelo (por ejemplo: impreso de consentimiento informado)

d) Asesoramiento técnico de expertos

e) Sistemas de control de calidad, asesoramiento especializado de calidad, etc.

f) Establecimiento de redes entre registros y partes interesadas

g) Facilitar el acceso a fuentes de datos útiles

En caso negativo, ¿por qué?

a) El registro ya no se encuentra activo**.**

b) Los proveedores de datos dejaron de proporcionarlos (por cualquier razón)

c) Otros:_____

43. Por favor, escriba las palabras clave que mejor describen su registro (palabras clave que puedan ser utilizadas para la indexación en el Registro General de Registros PARENT (RoR):_____

48. Añada cualquier otro tipo de información adicional, comentarios, ideas, etc. que desee: _____

Estimado titular de Registro, el cuestionario ha llegado a su fin. En caso de que no haya sido capaz de responder a alguna de las preguntas, por favor, guarde el cuestionario y podrá terminarlo tras consultar a sus colegas. Si le parece que es otra, la persona más adecuada para terminar este cuestionario, por favor, proporciónenos aquí su información de contacto y le enviaremos a dicha persona este ejemplar, que ya incluye las respuestas que usted ha proporcionado. ¡El equipo de PARENT le agradece el tiempo que ha dedicado a la realización de este importante cuestionario!

GUARDAR / ENVIAR / COMPARTIR