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Deliverable N. 9

Protocol for the Orthopaedic Pilot study

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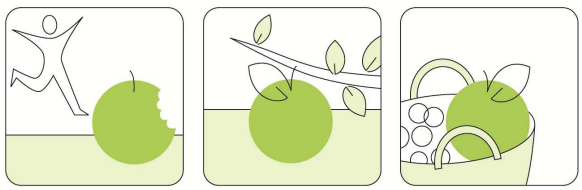

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National and Kapodistrian University of Athens, *Greece*

Genetics Research Institute ONLUS, *Italy*

ASL RM E Department of Epidemiology, *Italy*

Institut Municipal d'Assistència Sanitària, *Spain*

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Catalan Agency for Health Technology Assessment and Research, *Spain*

Slovak Arthroplasty Register, *Slovak Republic*

Arthroplasty Register Tyrol, *Austria*

Ludwig Boltzmann Institut Health Technology Assessment, *Austria*

French Society of Orthopaedic and Trauma Surgery, *France*

BQS Bundesgeschäftsstelle Qualitätssicherung gGmbH, *Germany*

Israel Society for the Prevention of Heart Attacks at NCRI, *Israel*

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Summary Report Orthopaedic Pilot

Background

Following health provisions introduced in the article 129 (Maastricht Treaty) and then in the article 152 (Amsterdam Treaty) the EU promoted a health strategy which gave rise to the Programme of Community Action in the Field of Public Health (2003-2008).

The Programme, adopted by the European Parliament and Council on 23 September 2002, was defined with the overall aim "to protect human health and improve public health". It includes three strands of action:

- To improve information and knowledge for the development of public health
- to enhance the capability of responding rapidly and in a coordinated fashion to health threats
- to promote health and prevent disease through addressing health determinants across all policies and activities

Funded under the Programme, the EUPHORIC project focuses on the first strand pursued by means of actions and support measures such as "developing and operating a sustainable health monitoring system" to establish comparable quantitative and qualitative indicators at community level on the basis of existing work and of accomplished results A survey will be conducted to make an inventory of the outcome research studies and indicators existing in the participant countries.
The European Arthroplasty Register (EAR; www.ear.efort.org) was invited to join the project after the withdrawal of the Heart Foundation of Austria on the basis of its experience and being a network of Arthroplasty Registers in Europe, established in an EFORT-Project since 2002.
On 31.12.2007 23 National Arthroplasty Registers in 19 countries were participating the project, EAR staff was involved in the development of the majority of them founded after 2000.

The major aims of the EAR and its contribution to the EUPHORIC project are:

1. To make the experience and results of the development of Arthroplasty Registers, starting in 1975, available for the EUPHORIC project. This includes the development of indicators and access to information acquired during a long period of development of complex National Arthroplasty Register (NAR) structures.
2. To develop Arthroplasty Registers and carry out methodological research in order to make these data-sources available for the Health System in the European Union, particularly in outcome related research

One main observation dealing with Arthroplasty Registers is that they have proven their efficacy in terms of improvement of outcome of arthroplasty procedures on national level, but their development was mainly independent from each other, so that the level of standardisation and supranational comparability is limited. In consequence the contribution to EU level monitoring systems and outcome measurement is currently limited without adjustment.

Objectives of the orthopaedic pilot study

1. To develop outcome indicators for Arthroplasty based on the existing national projects according to the requirements of ongoing European Commission projects.
2. To summarise the existing projects and the essential issues for success.
3. To define best practice procedures for the development and operating of Arthroplasty Registers.

4. To validate the potential contribution of different instruments in outcome measurement and quality monitoring of medical devices (i.e. Registers, Meta-analyses of clinical studies, Implant failure monitoring systems by the public health institutions, Quality control and complaint handling systems by the manufacturers) for a structured outcome measurement and quality control system in EU level
5. To present a detailed description of the outcome related Registers and similar datasets in 2 countries (Sweden, Finland) with a mature and advanced system in Europe in order to study the organisation and function of the entire outcome and quality monitoring system on national level.

Activities to be conducted:

1. To develop outcome indicators for Arthroplasty

Methodology

A The Indicators were developed based on the existing and well performing NAR in Europe.
Validation was – in contrary to the CV-pilot study – not necessary since they were already proven by National Arthroplasty Registers in Scandinavia. But they had to be defined according to the requirements of the ECHIM projects in order to fit to the EU terminology and requirements. Two main indicators were delivered and accepted (Annex 1).

The Indicators collected in the first phase of the EUPHORIC project (E1-E7) will be validated concerning their value for outcome research by a literature review and a statement from medical expert´s point of view, which will be available in the final report.

Deliverable

- Indicator sheets according to the ECHIM requirements
- A report concerning the value of the orthopaedic indicators E1 – E7
- A summary report on evaluations, which are possible by now for the orthopaedic indicators, which are proven to be valid for outcome measurement

2. Summary of existing projects on national level and key issues for success

Methodology

A structured and detailed assessment of all relevant National projects will be performed.
This will include successfully performing projects as well as projects failed in the past, recently founded projects and concepts to be started soon.
This evaluation will include

1. Detailed information on key persons, addresses, e-mail contact and www-pages for information
2. Detailed information about the organisation and internal mechanisms in data collection, data handling, evaluation and publication as well as connections to other partners.
3. Detailed information about the History of the Register including the development of forms and indicators by time
4. A description of the validation procedures
5. A description of the implant tracking procedures

The Questionnaire is attached (Annex 2)

Deliverable

1. A Report including a detailed summary report on existing projects on national level, which might be combined to a EU-wide monitoring tool and an assessment on their present level of development.
2. A Report including best practice procedures for development and operating Arthroplasty Registers and a Manual for people, who are in charge to develop such a project.

3. Definition of best practice procedures for the development and operation of a National Arthroplasty Register

Methodology

Based on the Information collected in the assessment described at point 2. a best practice procedure including key issues will be conducted.
Experts from existing Arthroplasty Registers will be included as reviewers in the EAR network.

Deliverable

A Manual for people, who are in charge to develop an outcome related Register.

4. Validation of different instruments available for outcome assessment of medical devices

Methodology

This activity will include several independent topics:

1. A structured literature review to evaluate the validity of Meta-analyses of clinical studies in comparison to Register reports for the detection of inferior outcome or inferior quality of products
2. A review of standard operating procedures of medical devices Manufacturers for complaints handling and their way of dealing with potential inferior outcome of their products
3. A review of public health related reporting systems for medical device failure in order to study their validity and impact for the detection of inferior quality compared to structured data collection like Registers.
4. A study concerning advanced methods in outcome related data collection like clinical scores included in Register documentation.

Deliverable

1. A Report concerning the validity of different instruments in outcome measurement, particularly for the detection of inferior performance and a proposal for an advanced system

The draft version of the questionnaire concerning the assessment of public health related reporting systems for medical device failure is attached in Annex 3

5. Description of the outcome research and quality monitoring system in advanced countries

Methodology

The partners KAR (Sweden) and STAKES (Finland) will prepare a summary report of all relevant outcome related registers in their country and the way of cooperation between them in order to present how the entire system works on national level in advanced countries.

Deliverable
A Report describing the systems in the countries as best practice procedures for the entire EU and a statement on differences between the countries as well as essential issues for the success of the entire system.

The questionnaires are attached in Annex 4.

Reference Glossary

EFORT: European Federation of National Associations of Orthopaedics and Traumatology (www.efort.org)

Annexes

1. Detailed sheets of orthopaedic indicators submitted to ECHIM
2. Questionnaire for the assessment of all relevant Arthroplasty Registers in Europe
3. Draft version of the Questionnaire for the assessment of public health related monitoring systems for implant failure.
4. Questionnaire for the assessment of the outcome research system in Sweden and Finland in the public health sector

ANNEX 1
Detailed sheets of orthopaedic indicators submitted to ECHIM

ECHIM *Indicator name*	**B) Health status** Revision Rate
Definition for indicator	Rate of Revision surgery (ICD9-CM: 81.53) at a defined follow up period.
Calculation of the indicator (numerator, denominator)	NUMERATOR: Number of Revisions (= Exchange or removal of at least a part of the implant) at Follow up period X DENOMINATOR: Total Number of primary implantations included in the evaluation sample
Additional underlying concepts	Definition of a revision is when at least a part of the implant has to be removed. Thesaurus: Survival rate (=1 - Revision rate) is often used as a synonym This indicator is presented at Kaplan-Meier Survival curves with the follow up period at the x-axis and an implant of surgical procedure at the y-axis. For adjustment in general Cox-regression analyses are used, but these procedures are not standardised by now in detail in the different national and regional European projects.
Relevant dimensions (subgroups)	In general the charts are adjusted to influence factors like gender, age or geographical regions.
(preferred) data source(s)	Arthroplasty Registers
Rationale	The goal of lifelong proper function is of highest importance for the exception by the patient, but also by surgeon and public health institutions. Even most of the patients are able to meet these exceptions the number of failures should be decreased to a minimum. The differences in revision rates between implants, medical procedures and health systems are high and have multifactor reasons. In general the time period between primary surgery and revision surgery has a high variety and a long term perspective. Revision surgery is a relatively rare procedure, but related with high impact on the quality of life of the patient and high costs for the public health budgets. According to an agreement among orthopaedic societies an up to date implant is required to have at least 95% survival rate after 10 years of follow up (= max. 5% revision rate). Additionally to the crude revision rate it is important to get access to information about the reasons for failure for analyses and quality control issues.
Data availability, quality, periodicity	By the present date data at national level are available in countries running a national arthroplasty register. A summary of information is available online at the EFORT-portal (http://www.efort.org/E/05/01-50.asp). The evaluation methods are similar, but not completely standardised.
References	Consensual agreement at the Scientific Board, European Arthroplasty Register (EAR www.efort.ear.org)
Work to do	The EUPHORIC-project final report will include a summary of the evaluation methods and a proposal for a future standard. The National Arthroplasty Registers in Europe are already included in a cooperation network, the European Arthroplasty Register (EAR). Common standards can be introduced by this way. A European structure for hosting the data, evaluations and reporting should be developed. EAR already started to establish procedures, achieve the agreement of the national partners and to sign contracts to realise the legal base for the transfer of data, data security and data handling. This activities should be synchronised with EU-requirements and activities.

ECHIM *Indicator name*	**B) Health status** Revision Burden Rate
Definition for indicator	Ratio between revision surgery and all the interventions in a defined geographical area
Calculation of the indicator (numerator, denominator)	NUMERATOR: Number of Revisions (= Exchange or removal of at least a part of the implant) in a period DENOMINATOR: Number of primary and revision operations in the same period
Additional underlying concepts	Definition of a revision is when at least a part of the implant has to be removed.
Relevant dimensions (subgroups)	This indicator is presented as a ratio referring to periods and geographical regions in general. This indicator could be used for defined cohorts of institutions too, but a proper adjustment to the background referred is recommended
(preferred) data source(s)	Arthroplasty Registers, Discharge Records, if comprehensive Register datasets are not available.
Rationale	The goal of patients, physicians and health institutions when implanting a medical device is in high amount to remain in the human body the entire life time. Based on this precondition every revision surgery related to the medical device has to be stated as a failure. The ratio between revisions and all the interventions is a valid general indicator concerning the quality of the medical service. Some limitations should be taken into consideration, first the fact that for most of the medical devices the period between primary intervention and revision surgery is long. Changes in the numbers of primary operations have an impact on the revision burden figures. Increasing numbers of primary implantations are decreasing the revision burden figures since the number of revision is based on a minor cohort from the past. For interpretation of revision burden figures it is recommended to take the development of primary interventions into account.
Data availability, quality, periodicity	Currently this indicator can be calculated from the information included in the annual report of National Arthroplasty Registers for the countries running specific projects. A summary of websites is available online at the EFORT-portal (http://www.efort.org/E/05/01-50.asp). Since not all the National Arthroplasty Registers have already published Reports, additional information has to be requested by direct contact. The European Athroplasty Register network is routinely in contact with all the national projects and confirms its cooperation on these activities. Discharge records are an other possible data source, but with inferior quality due to a less accurate definition of the intervention mainly in revision surgery. The main advantage in using this dataset is the interoperability since in this way it should be possible to collect standardised information in all countries due to the standardisation and common use of ICD-codes.
References	Consensual agreement at the Scientific Board, European Arthroplasty Register (EAR www.efort.ear.org)
Work to do	Description of a data collection and evaluation procedure and available data sources. Development of Arthroplasty Registers in all EU member states.

ANNEX 2
Questionnaire for the assessment of all relevant Arthroplasty Registers in Europe

Introduction

Outcome measurement is a major goal for public health and scientific purposes. Registers are an important tool for data collection and evaluation.

Aim of the EU project EUPHORIC, where the present form is part of the evaluation, is to study existing projects in detail in order to define best practice procedures for the design and development of future projects and to determine key factors for success and failure of these complex and large scale projects.

Additionally to the publication of the assessment as a feedback mechanism for present and future experts in the field of Register documentation, a list of reference centres and special expertise in specific issues will be available in the EUPHORIC orthopaedic pilot final report.

The terms “country” or “National” refer to the geographical area covered by a register. For regional registers, please add a note for the exact area covered and consider the regional register as relevant.

Basic Data

Country:……..

Name of the Register:……

Abbreviation:……
engl.:……..

Address:…….

e-mail address:……

Website:……

Contact person

Legal Status:

- ☐ Society
- ☐ Project of Public health Institutions
- ☐ Foundation
- ☐ Research Project of……..

Staff

- Head:

Employed by:

Responsibilities:

- Supervisory Board:

Name	Function	Responsibility	Employed by

- Medical staff:

Name	Function	Responsibility	Employed by

- Statistician:

Name	Function	Responsibility	Employed by

- Administrative Staff:

Name	Function	Responsibility	Employed by

- IT-Staff:

Name	Function	Responsibility	Employed by

- Other relevant staff or boards:

History of the Register

First outcome related Register in the country started:

Which one?

Past projects:
(years, name, reason for failure)

Initiative started for present Register: (year, which)

Decision to set up the register (year, who):

Start of the Pilot project:

Start of the National Data collection:

Receive > 75% compliance:

Receive > 90% compliance:

Validation process started (year):

Strategy for Validation used:

Sources of information used for validation:

Validation published (year, title):

First publication of the Register in a peer reviewed journal (year, title, journal):

First annual Report (specify year, title, on line availability if any):

Start feedback mechanisms to partners (year):

Initial funding:

Later funding:

Start present funding:

Inhouse / Outsource

Which activities are done by the core team in the Register itself, which activities are outsourced and to whom?

	Inhouse	Outsource
Data collection		
Databank basic		
Databank adjustment		
Statistical evaluations		
Printing		
Validation		

Data collection

Basic philosophy:

- ☐ Outcome research related
- ☐ Not outcome research related

Main goal of the Register:

Starting point of Documentation (initial data collection):

Follow up/Reference data collection:

Physical location of the databank:

- ☐ Network
- ☐ Online-server
- ☐ Offline server
- ☐ Not connected workstation

Software used:

Hardware used:

IT - Data security at the server (firewalls):

Data security backup:

Access to data (persons, PIN-restricted):

Processing of information collected:

- ☐ Paper forms processed by
- ☐ Fax processed by
- ☐ Informatics support (Floppy, CD) processed by
- ☐ Online
- ☐ Others

Data collection in Hospitals (if > 75% of all Hospital have 1 solution, please select this one exclusively, if there are different ways please specify their share):

- ☐ Information collected redundant (= Paper forms filled by the surgeon even the information is already available in the inhouse IT system)
- ☐ Excerpt from an existing dataset (= automatic excerpt from information collected for other purposes in the hospital IT system)
- ☐ Mixed data collection (= automatic excerpt from information collected for the Register in the hospital IT system

Proposed time for data collection:

- ☐ Hospitalisation
- ☐ Before surgery
- ☐ After surgery
- ☐ Discharge
- ☐ After discharge
- ☐ Clinical control/FUP examination
- ☐ Questionnaires to patients periodically sent?.....

Data collection procedures at starting point (in general)

- ☐ By surgeon at the operating room
- ☐ Review of the medical history at discharge
- ☐ By nurses

Data collection procedures at Follow up (in general):

- ☐ By surgeon at the controls
- ☐ Retrospective Review of the medical history
- ☐ By nurses

Plausibility checks at documentation?

Which, Where?

Connection to other databanks/data sources

- ☐ Discharge Register:

- ☐ Inhabitants Register /Deceased persons:
- ☐ Clearing of the data …… a year
- ☐ Economical data:
- ☐ Others:

Legal status of the data collection:

- ☐ Patient consent mandatory
- ☐ Permission by law
- ☐ Official project of a public institution under special conditions concerning data collection
- ☐ Quality Control project by……..

Participation to the Register:

- ☐ Mandatory
- ☐ Voluntary

Actions to support participation:

Owner of the data:

Validation

Number of departments performing Arthroplasty

Number of Departments in cooperation with the Register:

% of Departments included:

% of Market covered (Number of Cases):

% of cases/implants/patients collected at the Register database referring to the total number in the area in the previous year (Report)

% of clinicians reporting to the Register / total number of physicians performing Arthroplasty

Validation procedures of the Register

- ☐ Routine
- ☐ Publications

Implant tracking

Implant Databank:

Connection to the Register Databank:

Information collected:

- ☐ Implant name
- ☐ Article number
- ☐ Lot-Number
- ☐ Implant specifications

Size:

Maintenance:

Organisation and Management of the Implant databank:

Access of Stakeholders to not published datasets

Public Health Institutions:

- ☐ Ministry of Health
- ☐ Regional Public Health Institutions
- ☐ Public Health Insurances:
- ☐ Private Health Insurances:
- ☐ Manufacturers:
- ☐ Patients:

Physicians:

- ☐ Own Department
- ☐ For Revisions
- ☐ All data

Others:

Extraordinary Reports on Demand:

Implants

	Since	Nr/year	Total
Hip:			
Total:			
Partial:			
Knee:			
Total			
Monocondylar:			
Ankle:			
Shoulder:			
Elbow:			
Toe:			
Wrist:			
Finger:			

Evaluations

Definition of Revision (Endpoint)

Indicators calculated:

Statistical methods:

Additional clinical forms:

Which?

Participation:

Activities to achieve complete response/participation:

<u>Documentation of Revisions (more than one reason):</u>

- □ Multiple Choice (equal):
- □ Algorithm how to select the main reason:
- □ Main reason defined by the surgeon/centre:

  How?

<u>Strategy of Analyses:</u>

Who is defining the Strategy of Analyses:

Who is performing the analyses?

Statistical methods:

Review process and Reporting

Preparation of the first Report (persons, time frame, access to information)

Review processes before establishing the final Annual Report

Preparation of the department Report:

- □ Review process by the core team:
- □ Automatic generation:

Data Publication

Annual report: in English: Yes / No

Scientific Publications:
(Literature list, www-adress where available, if possible)

Extraordinary Reports on Demand (perhaps it could be put with the reports):

Impact and external Auditing

Impact of the Register for the

Sponsors

Public Health

Physicians:

Patients:

Quality control activities / feedback

Regular meetings:

External auditing?

Parameters

Main parameter (main target):

Main indicator evaluated:

Parameters included in the departments report:

Structure of the departments report:

Access to the departments report, delivery by……

Present data collection forms:

How and who conceived?

Modifications of the forms:

Which additional parameters?

When?

Why?

Additional benefit:

Quitted Parameters:

When?

Why?

Retrospective view?

Present and Historical Forms:

Budget

Global Budget:

Covered by:

Expenses:

Personnel:

Travel and accommodation:

IT

Outsource service

Historical reports

ANNEX 3
Draft version of the Questionnaire for the assessment of public health related monitoring systems for implant failure

Introduction

Reporting about medical device failure is an important tool to assure the quality of products by now.

Even the reporting is mandatory by law it is a matter of debate if these systems are working sufficiently and which level of failure they are able to detect.

This questionnaire is designed for a web-based or personal data collection. It can be rearranged concerning the sequence of question according to the personal preferences, but for the common data collection in an xls-file a common matrix should be used.

Basic Data

Country:Name of the Organisation:

Abbreviation engl. Local language:

Address:

e-mail address:

Website:

Contact person:

Access to information:

Webpage:

Contact person:

Other way:

Source of information used for the assessment:

(Report, year, access)

Evaluation on demand, communication based on data from…….

Implant fractures reported (Only Total Hip Implants!!)

Stem fractures:

Implant	Nr Fx reported	Nr. Implanted (if available)

Head Fractures:

Implant	Nr Fx reported	Nr. Implanted (if available)

* please specify the material, ceramic or metal

Cup Fractures:

Implant	Nr Fx reported	Nr. Implanted (if available)

Liner Fractures

Implant	Nr Fx reported	Nr. Implanted (if available)

Nr. of primary operations performed in the country/ year:

Nr. of revision operations performed in the country/year:

ANNEX 4
Questionnaire for the assessment of the outcome research system in Sweden and Finland in the public health sector

Introduction

Outcome measurement is a major goal for public health and scientific purposes. Registers are an important tool for data collection and evaluation.

Aim of the EU project EUPHORIC, where the present form is part of the evaluation, is to study existing projects in detail in order to define best practice procedures for the design and development of future projects and to determine key factors for success and failure of these complex and large scale projects.

Additionally to the publication of the assessment as a feedback mechanism for present and future experts in the field of Register documentation, a list of reference centres and special expertise in specific issues will be available in the EUPHORIC orthopaedic pilot final report.

The terms “country” or “National” refer to the geographical area covered by a register. For regional registers, please add a note for the exact area covered and consider the regional register as relevant.

Basic Data:

Country:……..
Name of the Register:……

Abbreviation:……
engl.:……..

Address:…….

e-mail address:……

Website:……

Legal Status:

☐ Society

☐ Project of Public Health Institutions

☐ Foundation

☐ Research Project of…….

Staff:

Head: (name)

Supervisory Board: (Name and Institution if available)

Medical staff: (number)

Statisticians: (number)

Administrative Staff: (number)

IT-Staff: (number)

History of the Register

Initiative for present Register started in (year):

Decision to set up the register (when, who):

Start of the Pilot project:

Start of the National Data collection:

Received > 90% compliance:

Validation process started in (year)

Validation published in (year):

First publication (specify year, title):

First annual Report (specify year, title, on line availability if any) :

Start of the feedback mechanisms to partners (year):

Initial funding by:

Data collection

Basic philosophy:

- □ Outcome research related
- □ Not outcome research related

Main goal of the Register:

Starting point of Documentation (initial data collection):

Follow up/Reference data collection:

Physical location of the databank:

- □ Network
- □ Online-server
- □ Offline server
- □ Not connected workstation

Processing of information collected:

- □ Paper forms processed by
- □ Fax processed by
- □ Informatic support (Floppy, CD) processed by
- □ Online
- □ Others

Data collection in Hospitals:

- □ Information collected redundant
- □ Excerpt from an existing dataset
- □ Mixed data collection

Proposed time for data collection:

- □ Hospitalisation
- □ Before surgery
- □ After surgery
- □ Discharge
- □ After discharge
- □ Clinical control/FUP examination

□ Questionnaires periodically sent to the patients?.....

Legal status of the data collection:

□ Patient consent mandatory

□ Permission by law

□ Official project of a public institution under special conditions concerning data collection

□ Quality Control project by……..

Participation in the Register:

□ Mandatory

□ Voluntary

Actions to support participation:

Owner of the data:

Number of Departments in cooperation with the Register:

% of Departments included:

% of Market covered (Number of Cases of the specific medical service):

Validation

% of cases/implants/patients collected in the Register database the total number in the area in the previous year (Report)

% of clinicians reporting to the Register / total number of physicians performing Arthroplasty

Validation procedures of the Register

□ Routine

□ Publications

Connection to other databanks/data sources

□ Discharge Register:

- ☐ Inhabitants Register /Deceased persons
- ☐ Access possible
- ☐ Causes of decease available?:
- ☐ Clearing of the data …… a year
- ☐ Economical data:
- ☐ Others:

Access of Stakeholders to not published datasets

Public Health Institutions:

- ☐ Ministry of Health
- ☐ Regional Public Health Institutions
- ☐ Public Health Insurances:
- ☐ Private Health Insurances:
- ☐ Manufacturers:
- ☐ Patients:

Physicians:

- ☐ Own Department
- ☐ For Revisions
- ☐ All data

Others:

Extraordinary Reports on Demand:

Evaluations

Definition of Endpoint:

Indicators calculated:

Statistical methods:

Data Publication

Annual report: in English: Yes / No

Scientific Publications:
(Literature list, www-address where available, if possible)

Extraordinary Reports on Demand (perhaps it could be put with the reports):

Impact and external Auditing

Impact of the Register for the

Sponsors

Public Health

Physicians:

Patients:

Quality control activities / feedback

Regular meetings:

External auditing?

Collected Variables:

Main parameter (main target):

Additional present parameters (engl. Translation of the present form in an Annex)

Parameters included in the regular reports:

Present data collection forms:

How, when and by whom the form was decided?

Budget:

Global Budget (if available):

Covered by: