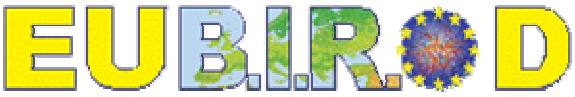
Directorate-General for Health & Consumers

Executive Agency for Health and Consumers



EUropean Best Information through Regional Outcomes in Diabetes

WORK PACKAGE 5

D5.1: COMMON DATASET

DOCUMENT V1.4

August 2010

This report is Deliverable D5.1 of "WP5: Data Collection" of the European project "European Best Information through Regional Outcomes in Diabetes" (EUBIROD), co-funded by DGSANCO, European Commission, 2008 (G.A. 2007115)

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Citation
Cunningham SG, Brillante M, McAlpine RR, Morris AD, Di Iorio CT, Adány R, Azzopardi J, Battelino T, Beck P, Boran G, de Beaufort C, Debacker N, Jarosz-Chobot Przemyslawa K, Jecht M, Lindblad U, Metelko Ž, Olympios G, Pruna S, Røder M, Skeie S, Storms F, Whiting D, Massi Benedetti M and Carinci F, Common Dataset, EUBIROD Consortium, 2010

Contents

1. Summary

The purpose of EUBIROD Deliverable 5.1 is to use the framework developed by the BIRO project and adapt it for use by a wider set of users, applying standards that can be validated and routinely applied. An analysis of all datasets maintained in the participating regions has been conducted, including an overview of the data format used to collect clinical data, levels of completeness, consistency with definitions and perceived levels of quality.

This work will define a minimum common dataset that is applicable to all EUBIROD partners in the context of their existing datasets. All metadata captured will be made available for local and national reporting. This analysis and review means that the underlying data schema must be updated and revised accordingly. As recommended in the BIRO D4.2 evaluation the schema has been revised and re-factored to incorporate a more formalised structure to prevent erroneous input.

2. References

BIRO Project Website: www.biro-project.eu

BIRO WP2 Clinical Review Indicator Development Results

BIRO WP3 Common Dataset

BIRO WP4 D4.1 Data Dictionary

BIRO WP4 D4.2 XML Metadata Dictionary

BIRO WP7 Reports Template

Chemistry Conversion: http://www.vin.com/scripts/labquest/converthtml.pl

Conventional Units to SI Units: http://www.globalrph.com/conv_si.htm

ESRI Shapefiles: http://www.esri.com/library/whitepapers/pdfs/shapefile.pdf
http://en.wikipedia.org/wiki/Shape_files

EUBIROD Project Website: www.eubirod.eu

Nomenclature of Territorial Units for Statistics:
http://en.wikipedia.org/wiki/NUTS

The BIRO Consortium (2009) *Best Information through Regional Outcomes: a Shared European Diabetes Information System for Policy and Practice*. The BIRO Consortium, European Commission:
http://www.eubirod.eu/documents/downloads/BIRO_Monograph.pdf

3. Document Change History

Version	Date	Author	Reason for Update
0.1	July 2010	Scott Cunningham	Initial Draft
1.0	August 2010	Scott Cunningham	Update for first version of deliverable after local review and partner comment
1.1	August 2010	Scott Cunningham	Final review for deliverable submission
1.2	August 2010	Scott Cunningham	Updates following comments from the co-ordinating centre, including new paediatric data items
1.3	October 2010	Scott Cunningham	Final updates for deliverable submission following partner feedback. Boundary data values added for all items.
1.4	November 2010	Scott Cunningham	Formatting aligned to EUBIROD standard

4. Methodology

BIRO Work Package 2 created a list of Core Indicator Candidates based on the published scientific literature in relation to diabetes. Within this, the justification for each of the corresponding data items was included. The subsequent BIRO Common Dataset was defined on the basis of the compatibility of each clinical parameter across each dataset after thorough analysis and cross-reference. The objective of this exercise was to identify consistencies and inconsistencies with the recording of data items and to create a universal definition across Europe for each of the items comprising the dataset. Where 100% correlation was not possible, a series of data mappings were specified to ensure compatibility with the Common Dataset. Where possible, data item definitions were compared in order to create one universally acceptable definition. This was the first time that a diabetes dataset with corresponding data definitions had been created for a European Population.

The EUBIROD project builds upon this work by further analysing the data for consistency with the datasets available to all 20 EUBIROD partners. For this, local knowledge was required from each of the partners regarding the constituent parts of their data repositories. This local knowledge is essential when describing the information available and provides enhanced metadata when compared to the analysis of data structures alone.

In order to capture this information, a web questionnaire application was created to capture local information related to each item in the dataset and its corresponding definition. If any deviations or anomalies were present, this information could be recorded against the dataset parameter by each partner. As this questionnaire is available online, it enables partners to update their local information as their datasets evolve. This information is a key resource which will be available when presenting results in the final report, potentially explaining discrepancies in data comparisons. A further benefit of this electronic storage is that validated, consistent local data source XML files can be created based on the input.

Partners completing their analyses and contributing to this process were as follows:

- Austria
- Belgium
- Croatia
- Cyprus
- Germany
- Hungary
- Ireland
- Italy
- Kuwait: currently no information system available
- Luxembourg: currently no information system available
- Malta

- Norway
- Romania
- Scotland
- Slovenia
- Sweden

Partners who had not contributed at the time of publication were:

- Denmark
- Netherlands
- Poland
- Spain

A systematic review and analysis of partner responses was then performed to identify commonality and inconsistencies with the local data items captured by each partner. This analysis is detailed and summarised in this deliverable.

5. Data Source Analysis Questionnaire

The EUBIROD Data Source Analysis Questionnaire was one of the key elements of this work package, capturing local knowledge not documented or readily available elsewhere. While the BIRO analysis focused more closely on an analysis of existing datasets and structures, EUBIROD aimed to enhance this by capturing enhanced, unpublished, metadata.

Each partner was furnished with a user identifier, password, user guide (see Appendix 1) and web address to allow them to enter their local information. This authorised them to provide a low-level description of confounding factors and to outline discrepancies in data collection, manipulation and data storage. It remains online to allow easy maintenance and update. The information collected provides extremely powerful and unique commentary on the web outputs created by the Central BIRO Engine.

The online questionnaire consists of 5 main sections:

5.1 Login and Data Source Selection

Within each partner country, one or more local data sources may be described and documented. Once the user has logged on to their account, they will be shown the existing data sources that they can edit, but also have the opportunity to add a new source for their country.

5.2 Site Header

The second section allows for the entry of the administrative contact details associated with the specific data source. This allows partners to distribute responsibility for sub-regional data sources within their country.

5.3 Site Profile

This section allows the entry of some aggregated data related to the data source being described. These may not be relevant for all data sources, but for each clinical data source (e.g. DARTS, Umbria) this is necessary.

5.4 Field Export Profiles

For each data item within every source, EUBIROD needs to obtain information about the data quality, completeness and consistency with the EUBIROD definitions. Definitions of each of these measures can be found in the BIRO Monograph (http://www.eubirod.eu/documents/downloads/BIRO_Monograph.pdf), although they are briefly covered in Appendix 2. It was important that the designated partner representative entering the data into this section had considerable in-depth knowledge regarding data quality and completeness within their designated area. Particularly useful is the free-text comments section which allows the user to provide a commentary on any issues or features they are aware of contained within their local data.

This data entered in this section can be used for further presentation alongside the final indicator outputs. A wizard-based application loops through every EUBIROD data item in turn until data is completed for each.

5.5 Summary of Data Entry

On completion of data entry, a summary screen is produced for review and validation. At this point, all data entered is stored to database, meaning that any future updates simply build on the data entered during the first submission.

The full data capture process takes no longer than 15 minutes the first time it is completed, although it may take longer to identify local data issues and percentages of completeness. As the system saves any previous submissions, subsequent action consists of only updating data items that have either changed or been added. It is recommended that all data source metadata is reviewed by a local representative at least annually.

5.6 Dynamic Documentation

As a result of the online data capture, it is possible for all descriptive data source XML documentation to be generated dynamically. This documentation is essential for transmission to the central engine for subsequent display online, and this process improves reliability, consistency and validity. The questionnaire results are captured in a database and from there they can be translated into the appropriate XML format. By aligning this with the agreed schema, validity checks can be performed during generation and in addition to reducing the manual overhead of creating these files, a consistent approach can be applied

6. Dataset Review: Analysis of Results

The following sections show the results produced by the questionnaire submissions for each of the EUBIROD clinical dataset items. These are the actual data entered by each partner. In addition to discussing the responses based on the current dataset, the next section in this report will comment on general observations and findings as a result of this exercise. Although Luxembourg is shown in the report detailing responses, this partner has no clinical information system at present as is ignored from the further discussion.

The outcome of each data item analysis will lead to the definition of a new 'Validity' rating. This concept was defined for BIRO, but has been modified in line with the increase in partners to the following:

Validity Classification: High
Definition: High Validity items are those which are consistent across ≥90% of analysed datasets

Validity Classification: Medium
Definition: Medium Validity items are those which are consistent across over ≥60% and <90% of analysed datasets

Validity Classification: Low
Definition: Low Validity items are those which are consistent across <60% of analysed datasets

6.1 Patient ID

Definition: Unique patient identification number assigned by centre (data source)

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	100%	High	Yes	Yes	No	
Belgium	Low	100%	Low	No	Yes	Yes	In the database that I am using for EUBIROD there is a patient id, however, it was assigned just for the EUBIROD purpose and does not allow in any way to identify the patient.
Croatia	High	100%	High	Yes	Yes	No	
Cyprus	High	100%	High	No	Yes	Yes	none
Germany	High	100%	High	Yes	Yes	No	
Hungary	Medium	100%	Low	No	Yes	Yes	We don't have a unique patient identifier. The code that you find in the database i a code recognised by the IPH and does not permit any link to the original patient
Ireland	High	100%	High	Yes	Yes	No	Unique identifier assigned by hospital PIMS system.
Italy	High	100%	High	Yes	Yes	No	
Luxembourg	Low	0%	Low	Yes	Yes	No	further data entry is not yet possible
Malta	High	100%	High	Yes	Yes	No	
Norway	High	100%	High	Yes	Yes	No	
Romania	High	100%	High	No	Yes	Yes	
Scotland	High	100%	High	Yes	Yes	No	
Slovenia	Medium	100%	High	Yes	Yes	No	
Sweden	High	87%	High	No	Yes	Yes	

Commentary: Although some partners do not have a global unique patient identifier that covers all data sources, a unique identifier is available to identify data associated with a patient from each source. This is sufficient for the purposes of EUBIROD, although care must be taken to ensure that patients attending multiple data sources are not counted more than once as this will affect prevalence figures, etc. As a result, record linkage and ‘data cleansing’ may be required by each of these partners.

Validity: High

6.2 Type of Diabetes

Definition:

Type 1: WHO 1999 revised classification: WHO Department of Noncommunicable Disease Surveillance. Definition, Diagnosis and Classification of Diabetes Mellitus and its Complications. Geneva: WHO; 1999. Available from URL http://whqlibdoc.who.int/hq/1999/who_ncd_ncs_99.2.pdf. Type 1 diabetes includes all diabetes due to absolute insulin deficiency caused by a) autoimmune pancreatic destruction and b) idiopathic where there is no evidence of autoimmunity or other identifiable cause.

Type 2: WHO 1999 revised classification: WHO Department of Noncommunicable Disease Surveillance. Definition, Diagnosis and Classification of Diabetes Mellitus and its Complications. Geneva: WHO; 1999. Available from URL http://whqlibdoc.who.int/hq/1999/who_ncd_ncs_99.2.pdf. Type 2 diabetes includes those forms of diabetes with insulin resistance and an insulin secretory defect.

Other: Other types of Diabetes Mellitus, not specifically Type 1 or Type 2

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	100%	High	Yes	Yes	No	
Belgium	Medium	100%	High	Yes	Yes	No	
Croatia	Medium	100%	High	Yes	Yes	No	In our database we distinguish type 1, type 2, other type, gestational and undefined
Cyprus	High	95%	Medium	Yes	Yes	No	
Germany	High	100%	High	Yes	Yes	No	
Hungary	Medium	100%	High	Yes	Yes	No	
Ireland	High	99%	Medium	No	Yes	Yes	Multiple categories available on our system: Type 1, Type 2, MODY, Secondary, Gestational, IGT, Type 1.5, IFG, IFG+IGT. Mapping required.
Italy	Medium	23%	Low	No	No	No	

Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	100%	High	No	Yes	Yes	
Norway	Medium	90%	Medium	No	Yes	Yes	We have: 1. Type 1 incl. LADA, 2. Type 2, 3. Other (incl. pancreatit and MODY) 4. Unknown
Romania	High	100%	High	No	Yes	Yes	
Scotland	High	100%	High	Yes	Yes	No	
Slovenia	High	100%	High	Yes	Yes	No	
Sweden	High	100%	High	No	Yes	Yes	

Commentary: As would be expected, general consistency with the World Health Organisation (WHO) classifications of diabetes type is high, although it is not clear why in Italy this is not the case. Most sources indicate that diabetes type is not recorded routinely, perhaps indicating that it is recorded once at diagnosis only. Discussion after submissions have indicated that there is desire to extend the types of diabetes available to EUBIROD. This will be assessed during the next phase of development.

Validity: High

6.3 Sex

Definition: Unique Male/Female Phenotype at birth

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	100%	High	Yes	Yes	No	
Belgium	High	100%	High	Yes	Yes	No	
Croatia	High	100%	High	Yes	Yes	No	
Cyprus	High	100%	High	Yes	Yes	No	
Germany	High	100%	High	Yes	Yes	No	
Ireland	High	100%	High	Yes	Yes	No	
Italy	High	100%	High	Yes	Yes	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	100%	High	No	Yes	Yes	
Norway	High	100%	High	Yes	Yes	No	
Romania	High	100%	High	No	Yes	Yes	
Scotland	High	97%	High	Yes	Yes	No	
Scotland	High	97%	High	Yes	Yes	No	
Slovenia	High	100%	High	Yes	Yes	No	
Sweden	High	100%	High	No	Yes	Yes	

Commentary: Patient gender has very high correlation with the EUBIROD definition.

Validity: High

6.4 Date of Birth

Definition: Date of birth of subject (ccyy-mm-dd)

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	100%	High	Yes	Yes	No	FQSD only records Date of Year and extends the year with '/01/01' to meet the item definition
Belgium	High	100%	High	Yes	Yes	No	
Croatia	High	100%	High	Yes	Yes	No	
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	High	100%	High	Yes	Yes	No	
Hungary	High	100%	High	Yes	Yes	No	
Ireland	High	100%	Medium	Yes	Yes	No	Our date format is: dd/mm/yyyy
Italy	High	100%	High	Yes	Yes	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	97%	High	Yes	Yes	No	
Norway	High	100%	High	Yes	Yes	No	
Romania	High	100%	High	No	Yes	Yes	
Scotland	High	100%	High	Yes	Yes	No	
Slovenia	High	100%	High	Yes	Yes	No	
Sweden	High	100%	High	No	Yes	Yes	

Commentary: Date of birth has very high correlation with the EUBIROD definition. Although a date format is defined, it has been agreed that only the year portion will be exported in a date format: i.e. 01/07/yyyy. A mid-year date is used so that the effect on age at diagnosis is minimised.

Validity: High

6.5 Year of Diagnosis

Definition: Date of Diagnosis of Diabetes Mellitus (ccyy-mm-dd)

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	100%	High	Yes	Yes	No	DATA is recorded as dd/mm/yyyy. If unknown datavalue is 01/01/1900
Belgium	Medium	95%	High	No	Yes	Yes	
Croatia	Medium	81%	High	No	Yes	Yes	
Cyprus	High	100%	High	Yes	Yes	No	
Germany	High	100%	High	Yes	Yes	No	
Hungary	Medium	90%	Medium	No	Yes	Yes	
Ireland	Low	33%	Medium	No	Yes	Yes	Our date format is: dd/mm/yyyy. Not consistently recorded.
Italy	High	100%	High	Yes	Yes	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	90%	High	No	Yes	Yes	Please note that our Year of Diagnosis is entered as a text file with only the year e.g 1994, entered. Hence our present format is imcompatable with the BIRO database.
Norway	Medium	80%	Medium	No	Yes	Yes	We have year of diagnosis, not date.
Romania	High	80%	High	No	Yes	Yes	
Scotland	High	100%	High	Yes	Yes	No	Due to multiple datasources recording date of diagnosis, some conflict occurs. SCI-DC processing attempts to pick the most logical date.
Slovenia	High	100%	High	Yes	Yes	No	

Sweden	Medium	60%	Medium	No	Yes	Yes

Commentary: Year of diagnosis has very high correlation with the EUBIROD definition. Although a date format is defined, it has been agreed that only the year portion will be exported in a date format: i.e. 01/07/yyyy. This addresses the concerns raised by partners who only capture year, with a mid-year date used so that the effect on age at diagnosis and duration of disease are minimised.

Validity: High

6.6 Episode Date

Definition: Date when information recorded - Every clinical field has an associated date of recording or event

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	100%	High	Yes	Yes	No	
Belgium	Low	100%	Low	No	Yes	Yes	The data that I use for EUBIROD was obtained through a data collection in about 115 centres. In the centres the date of the consultation is known, however I do not ask the date of the consultation in the data collection. The data originate from a consultation taking place in 2007, so I assigned to all patients 2007 as EPI_DATE
Croatia	Medium	100%	High	Yes	Yes	No	
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	High	100%	High	Yes	Yes	No	
Hungary	Not Recorded	0%	Not Recorded	No	No	No	
Ireland	High	100%	Medium	Yes	Yes	No	Our date format is dd/mm/yyyy.
Italy	High	100%	High	Yes	Yes	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	100%	High	Yes	Yes	No	
Norway	High	100%	High	Yes	Yes	No	
Romania	High	100%	High	No	Yes	Yes	

Scotland	Medium	99%	High	No	Yes	Yes	Some clinical/administration systems allow retrospective and prospective dates to be entered thus some errouneous dates can occur.
Slovenia	Not Recorded	0%	Not Recorded	No	No	No	
Sweden	High	100%	High	No	Yes	Yes	

Commentary: Every EUBIROD data item must have a date associated with it. For those sources when only year of extract is known, 01/07/yyyy is acceptable, although this metadata should be presented alongside outputs. A mid-year date is used to limit the effect of erroneous dates to a maximum of 6 months. It is not clear why Hungary and Slovenia do not record dates and further comments will be requested.

Validity: High

6.7 Smoking Status

Definition: Smoking status at date of contact 1 = Current Smoker 2 = Non-Smoker 3 = Ex-Smoker

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	95%	High	No	Yes	Yes	FQSD doesn't capture data about Ex-Smokers. Only NULL, 1, 2 are possible values
Belgium	High	93%	High	No	Yes	Yes	
Croatia	Medium	76%	Medium	No	Yes	Yes	In our database we distinguish 1 = Current Smoker and 2 = Non-Smoker
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	High	95%	High	No	Yes	Yes	FQSD doesn't capture data about Ex-Smokers. Only NULL,1,2 are possible values
Hungary	Medium	80%	Medium	No	Yes	Yes	
Ireland	Medium	75%	Medium	No	Yes	Yes	Multiple Categories available on our system: Never Smoked, Stopped, Passive, Cigarettes, Cigar, Tobacco. Mapping required.
Italy	Low	0%	Low	No	No	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	90%	High	Yes	Yes	No	Please note that ex smoker is recorded but is not being captured by the BIRO database. This is something we will correct at our end.
Norway	Medium	70%	High	No	Yes	Yes	We also have unknown as an answer. This is the matter in all our data items

Romania	High	80%	High	No	Yes	Yes	
Scotland	Medium	100%	High	Yes	Yes	No	Patient reported information that is difficult to verify and may differ between data sources.
Slovenia	Medium	50%	Medium	No	Yes	Yes	
Sweden	Medium	50%	Medium	No	Yes	Yes	

Commentary: There is varying quality in the recording of smoking status, confounded further by the fact that this is a patient reported data item that may be inaccurate. Many sources do not record 'ex-smoker' – it may be necessary in the first EUBIROD report to report only current and non-smokers, with ex-smoker mapped appropriately so that a more consistent analysis can be performed.

Validity: Medium

6.8 Cigarettes per Day

Definition: Number or estimate – 1 pipe = 3 cigarettes

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	95%	High	Yes	Yes	No	
Belgium	Medium	86%	Medium	No	Yes	Yes	
Croatia	Low	9%	High	No	Yes	Yes	
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	High	95%	High	Yes	Yes	No	
Hungary	Medium	80%	Medium	No	Yes	Yes	
Ireland	Medium	88%	Medium	No	Yes	Yes	We record Cigarettes/Cigars per day, Tobacco Oz./wk. Mapping required.
Italy	Low	0%	Low	No	No	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	99%	High	No	Yes	Yes	
Norway	Not Recorded	0%	Not Recorded	No	No	No	
Romania	High	60%	High	No	Yes	Yes	
Scotland	Medium	100%	High	Yes	Yes	No	
Slovenia	Not Recorded	0%	Not Recorded	No	No	No	
Sweden	Not Recorded	0%	Not Recorded	No	No	No	

Commentary: This data item is not well recorded, with 4 of the active partners not recording it all. Reporting overall smoking status is expected to give a better output for the EUBIROD report.

Validity: Low

6.9 Alcohol Intake

Definition: Alcohol intake per average week. Recording of a numerical value is preferred since recommended consumption limits are subject to periodic revision and may differ for pregnant women.

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	70%	High	Yes	Yes	No	
Belgium	Not Recorded	0%	Not Recorded	No	No	No	
Croatia	Low	1%	High	No	Yes	Yes	
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	High	70%	High	Yes	Yes	No	
Hungary	Not Recorded	0%	Not Recorded	No	No	No	
Ireland	Medium	65%	Medium	No	Yes	Yes	Recorded as units per week. Mapping required.
Italy	Low	0%	Low	No	No	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	Not Recorded	0%	Not Recorded	No	No	No	
Norway	Not Recorded	0%	Not Recorded	No	No	No	
Romania	High	80%	High	No	Yes	Yes	

Scotland	Low	10%	Low	Yes	Yes	No	The majority of results (67%) are recorded 0 (zero units) and this may be the deafault where the patients are not asked so some caution is required when interpreting these values.
Slovenia	Not Recorded	0%	Not Recorded	No	No	No	
Sweden	Not Recorded	0%	Not Recorded	No	No	No	

Commentary: This data item is not well recorded, indicating that meaningful analysis of alcohol intake is likely to be compromised.

Validity: Low

6.10 Weight

Definition: Body-weight of the patient in kilograms. Units:Kg

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	95%	High	Yes	Yes	No	
Belgium	High	98%	High	No	Yes	Yes	
Croatia	High	84%	High	No	Yes	Yes	
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	High	95%	High	Yes	Yes	No	
Hungary	High	100%	High	Yes	Yes	No	
Ireland	Medium	59%	High	No	Yes	Yes	Recorded in every clinic but not always entered on system.
Italy	High	100%	High	No	Yes	Yes	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	Medium	62%	Medium	No	Yes	Yes	
Norway	Medium	70%	High	No	Yes	Yes	
Romania	High	100%	High	No	Yes	Yes	
Scotland	Medium	92%	High	No	Yes	Yes	
Slovenia	Medium	80%	Medium	No	Yes	Yes	
Sweden	High	80%	High	No	Yes	Yes	

Commentary: Weight is generally consistent and well recorded across all partners.

Validity: High

6.11 Height

Definition: Height in metres - measured without shoes. It is particularly important to measure regularly the height of children. In adults a single recording will usually be sufficient.

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	95%	High	Yes	Yes	No	
Belgium	Medium	91%	Medium	No	Yes	Yes	
Croatia	High	88%	High	No	Yes	Yes	
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	High	95%	High	Yes	Yes	No	
Hungary	High	100%	High	Yes	Yes	No	
Ireland	High	87%	High	No	Yes	Yes	Recorded in every clinic but not always entered on system.
Italy	High	80%	High	No	Yes	Yes	cm
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	98%	High	No	Yes	Yes	
Norway	Medium	60%	High	No	Yes	Yes	
Romania	High	100%	High	No	Yes	Yes	
Scotland	High	90%	High	No	Yes	Yes	
Slovenia	Medium	80%	Medium	No	Yes	Yes	
Sweden	Medium	60%	Medium	No	Yes	Yes	We use centimetres. We can calculate into meters

Commentary: Height is generally consistent and well recorded across all partners with only simple mappings from centimetres to metres required.

Validity: High

6.12 Body Mass index

Definition: BMI = weight(kg)/height(m)^2 - units:kg/ m^2

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	90%	High	Yes	Yes	No	
Belgium	Medium	91%	Medium	No	Yes	Yes	
Croatia	High	83%	High	No	Yes	Yes	
Cyprus	High	100%	High	Yes	Yes	Yes	Automatically calculated when height and weight entered on system
Germany	High	90%	High	Yes	Yes	No	
Hungary	High	100%	High	Yes	Yes	No	
Ireland	Medium	54%	High	No	Yes	Yes	Automatically calculated when height and weight entered on system.
Italy	Medium	50%	High	No	Yes	Yes	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	98%	High	No	Yes	Yes	
Norway	Medium	60%	High	No	Yes	Yes	
Romania	High	100%	High	No	Yes	Yes	
Scotland	High	90%	High	No	Yes	Yes	
Slovenia	Not Recorded	0%	Not Recorded	No	No	No	
Sweden	High	75%	Medium	No	Yes	Yes	

Commentary: Body Mass Index is well recorded and consistent with the EUBIROD definitions. In some cases it may be possible to calculate this value from weights and heights supplied by partners.

Validity: High

6.13 Systolic Blood Pressure

Definition: Patient's blood-pressure in mmHg after 5 minutes rest in seated position with arm elevated/supported (Range: 70 – 300 or empty).Units:mmHg

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	95%	High	Yes	Yes	No	
Belgium	Medium	99%	Medium	No	Yes	Yes	
Croatia	Medium	68%	High	No	Yes	Yes	
Cyprus	Medium	85%	Medium	Yes	Yes	Yes	
Germany	High	95%	High	Yes	Yes	No	
Hungary	Medium	95%	Medium	No	Yes	Yes	
Ireland	Medium	58%	High	No	Yes	Yes	Recorded in every clinic but not always entered on system.
Italy	High	11%	High	No	Yes	Yes	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	Medium	63%	Medium	No	Yes	Yes	
Norway	Medium	90%	Medium	No	Yes	Yes	Our definition: The mean of the two last of three measurements. One minute between each of the three measurements.
Romania	High	80%	High	No	Yes	Yes	
Scotland	High	90%	High	No	Yes	Yes	
Slovenia	Medium	80%	Medium	No	Yes	Yes	
Sweden	High	90%	High	No	Yes	Yes	

Commentary: Good levels of completeness are reported across Europe with no problems raised with the EUBIROD definition. Those reporting ‘medium’ consistency will be asked to provide more detail.

Validity: High

6.14 Diastolic Blood Pressure

Definition: Patient's blood-pressure in mmHg after 5 minutes rest in seated position with arm elevated/supported (Range: 30 – 150 or empty)

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	95%	High	Yes	Yes	No	
Belgium	Medium	99%	Medium	No	Yes	Yes	
Croatia	Medium	68%	High	No	Yes	Yes	
Cyprus	Medium	85%	Medium	Yes	Yes	Yes	
Germany	High	95%	High	Yes	Yes	No	
Hungary	High	100%	High	Yes	Yes	No	
Ireland	Medium	58%	High	No	Yes	Yes	Recorded in every clinic but not always entered on system.
Italy	High	11%	High	No	Yes	Yes	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	97%	High	No	Yes	Yes	
Norway	Medium	90%	Medium	No	Yes	Yes	Our definition: The mean of the two last of three measurements. One minute between each of the three measurements.
Romania	High	80%	High	No	Yes	Yes	
Scotland	High	93%	High	No	Yes	Yes	
Slovenia	Not Recorded	0%	Not Recorded	No	No	No	
Sweden	High	90%	High	No	Yes	Yes	

Commentary: Good levels of completeness are reported across Europe with no problems raised with the EUBIROD definition. Perhaps surprisingly, some partners reported different levels of completeness and consistency when comparing systolic and diastolic blood pressures.

Validity: High

6.15 HbA1c

Definition: Current Glycated haemoglobin value in % (Range: 4 - 40, or empty)Units:%

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	90%	High	Yes	Yes	No	
Belgium	High	99%	High	No	Yes	Yes	
Croatia	High	72%	High	No	Yes	Yes	
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	High	90%	High	Yes	Yes	No	
Hungary	Medium	98%	Medium	No	Yes	Yes	
Ireland	High	95%	High	No	Yes	Yes	Our system has a direct LIS interface with the hospital lab. Some tests completed outside of the hospital lab service will be missing.
Italy	High	68%	High	No	Yes	Yes	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	Medium	77%	Medium	No	Yes	Yes	NB. In fact most patients have their lab investigations performed at least once a year. At present our laboratory results are recorded into a separate database and have to be typed manually into the diabetes database. Hence the low percentage.
Norway	High	90%	High	No	Yes	Yes	
Romania	High	50%	High	No	Yes	Yes	

Scotland	High	93%	High	No	Yes	Yes	Aug 2002, HbA1c was DCCT (%) aligned. In 2009, was IFCC aligned (mmol/mol). There is mapping in place for these.
Slovenia	High	90%	High	Yes	Yes	No	
Sweden	High	95%	High	No	Yes	Yes	

Commentary: Unsurprisingly, HbA1c is very well recorded across Europe. There has been some discussion regarding a move to using the IFCC aligned HbA1c measure. At this stage, HbA1c will continue to be captured and reported as a percentage with this to be reviewed when it is more universally available. A direct mapping between the two measures is possible in any case.

Validity: High

6.16 Creatinine

Definition: Serum creatinine value in µmol/l

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	80%	High	Yes	Yes	No	
Belgium	High	97%	High	No	Yes	Yes	
Croatia	Medium	67%	High	No	Yes	Yes	
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	High	80%	High	Yes	Yes	No	
Hungary	High	80%	High	Yes	Yes	No	
Ireland	High	95%	High	No	Yes	Yes	Our system has a direct LIS interface with the hospital lab. Some tests completed outside of the hospital lab service will be missing.
Italy	Low	0%	Low	No	No	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	82%	High	No	Yes	Yes	NB. In fact most patients have their lab investigations performed at least once a year. At present our laboratory results are recorded into a separate database and have to be typed manually into the diabetes database. Hence the low percentage.
Norway	Medium	60%	High	No	Yes	Yes	
Romania	High	40%	High	No	Yes	Yes	
Scotland	High	94%	High	No	Yes	Yes	

Slovenia	Not Recorded	0%	Not Recorded	No	No	No
Sweden	Medium	70%	Medium	No	Yes	Yes

Commentary: Creatinine is generally very well recorded and consistent with the EUBIROD definition.

Validity: High

6.17 Microalbumin

Definition: 1 = MA Test Normal 2 = MA Test abnormal 0 = No MA Test Recorded

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	100%	High	Yes	Yes	No	
Belgium	Medium	95%	High	No	Yes	Yes	
Croatia	Low	13%	Low	No	Yes	Yes	At present there is a field for albuminuria in 24h urine (mg/24h).
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	High	100%	High	Yes	Yes	No	
Hungary	Medium	85%	Medium	No	Yes	Yes	
Ireland	High	95%	Medium	No	Yes	Yes	Our system has a direct LIS interface with the hospital lab. Some tests completed outside of the hospital lab service will be missing. Numeric result on our system (0 – 25 mg/L), will have to be mapped.
Italy	Low	7%	Low	No	Yes	Yes	We have Microalbuminuria as a numeric field: mg/L
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	Low	40%	Low	No	Yes	Yes	
Norway	Medium	50%	Medium	No	Yes	Yes	
Romania	High	40%	High	No	Yes	Yes	
Scotland	High	96%	High	No	Yes	Yes	Due to multiple MA testing methodologies, MA is difficult to qualify. It is better to derive MA status from actual MA values.
Slovenia	Medium	70%	Medium	No	Yes	Yes	

Sweden	High	85%	High	No	Yes	Yes

Commentary: Due to multiple methods of recording urine microalbumin, a decision was taken to report only on normal and abnormal tests at this stage. For those partners who record specific values, these can be mapped.

Validity: Medium

6.18 Total Cholesterol

Definition: Serum total cholesterol can be either fasted or unfasted - units: mmol/L

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	80%	High	Yes	Yes	No	
Belgium	High	96%	High	No	Yes	Yes	
Croatia	High	72%	High	No	Yes	Yes	Usually serum total cholesterol in Croatia is measured while patient is fasted.
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	High	80%	High	Yes	Yes	No	
Hungary	High	80%	High	Yes	Yes	No	
Ireland	High	95%	High	No	Yes	Yes	Our system has a direct LIS interface with the hospital lab. Some tests completed outside of the hospital lab service will be missing.
Italy	Medium	17%	High	No	Yes	Yes	unit: mg/dL
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	83%	High	No	Yes	Yes	NB. In fact most patients have their lab investigations performed at least once a year. At present our laboratory results are recorded into a separate database and have to be typed manually into the diabetes database. Hence the low percentage.
Norway	High	90%	High	No	Yes	Yes	
Romania	High	40%	High	No	Yes	Yes	
Scotland	Medium	70%	High	No	Yes	Yes	

Slovenia	Medium	80%	Medium	No	Yes	Yes
Sweden	High	95%	High	No	Yes	Yes

Commentary: Very high consistency reported for total cholesterol.

Validity: High

6.19 HDL Cholesterol

Definition: Serum HDL cholesterol can be either fasted or unfasted - units: mmol/L

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	60%	High	Yes	Yes	No	
Belgium	High	94%	High	No	Yes	Yes	
Croatia	Medium	57%	High	No	Yes	Yes	Usually measured while fasted.
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	High	60%	High	Yes	Yes	No	
Hungary	Medium	90%	Medium	No	Yes	Yes	
Ireland	High	95%	High	No	Yes	Yes	Our system has a direct LIS interface with the hospital lab. Some tests completed outside of the hospital lab service will be missing.
Italy	Medium	16%	High	No	Yes	Yes	units: mg/dL
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	83%	High	No	Yes	Yes	NB. In fact most patients have their lab investigations performed at least once a year. At present our laboratory results are recorded into a separate database and have to be typed manually into the diabetes database. Hence the low percentage.
Norway	Medium	70%	High	No	Yes	Yes	
Romania	High	60%	High	No	Yes	Yes	
Scotland	High	93%	High	No	Yes	Yes	

Slovenia	Not Recorded	0%	Not Recorded	No	No	No
Sweden	High	90%	High	No	Yes	Yes

Commentary: HDL cholesterol is consistent with EUBIROD definition.

Validity: High

6.20 Triglycerides

Definition: Serum triglycerides value in mmol/L

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	75%	High	Yes	Yes	No	
Belgium	High	54%	High	No	Yes	Yes	We have TG for 95% of the patients, but only about 50% were fasting. It is not specified in the definition whether it concerns fasting or not. I assume it is fasting.
Croatia	High	71%	High	No	Yes	Yes	
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	High	75%	High	Yes	Yes	No	
Hungary	High	80%	High	Yes	Yes	No	
Ireland	High	95%	High	No	Yes	Yes	Our system has a direct LIS interface with the hospital lab. Some tests completed outside of the hospital lab service will be missing.
Italy	Medium	0%	High	No	Yes	Yes	units: mg/dL
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	83%	High	No	Yes	Yes	NB. In fact most patients have their lab investigations performed at least once a year. At present our laboratory results are recorded into a separate database and have to be typed manually into the diabetes database. Hence the low percentage.

Norway	Medium	60%	High	No	Yes	Yes
Romania	High	60%	High	No	Yes	Yes
Scotland	High	37%	High	No	Yes	Yes
Slovenia	Medium	80%	Medium	No	Yes	Yes
Sweden	High	90%	High	No	Yes	Yes

Commentary: The definition for Triglycerides is very consistent with the data available in each partner country. Clarification has been sought over whether this measurement should be fasted or unfasted. The answer is that both are acceptable and that the definition will be amended to reflect this.

Validity: High

6.21 Retinal Examination

Definition: 1=Yes: Fundus Examination Performed. 0=No:Year of Fundus Examination field is NULL or contains invalid numeric data.

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	Medium	95%	High	Yes	Yes	No	FQSD-Dataset only provides information of fundus examinations performed in the last 12 months
Belgium	Medium	99%	Medium	No	Yes	Yes	I only know whether a fundus examination was carried out during the data collection year, yes or no. It is not stored as the year when it was carried out.
Croatia	Low	17%	Medium	No	Yes	Yes	At present there is a field EYES=Examination in last 12 months (options Yes or No), with details of examination in subfields (retinopathy (Y or N), maculopathy (Y or N), etc.).
Cyprus	Medium	80%	Medium	Yes	Yes	Yes	
Germany	Medium	95%	High	Yes	Yes	No	FQSD-Dataset only provides information of fundus examinations performed in the last 12 months
Hungary	Medium	50%	Medium	No	Yes	Yes	
Ireland	Low	22%	Medium	No	Yes	Yes	Some mapping may be required. Should be carried out annually but not always possible. Not recorded in a consistent manner.
Italy	Not Recorded	0%	Not Recorded	No	No	No	

Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	80%	High	No	Yes	Yes	
Norway	Medium	50%	Medium	No	Yes	Yes	
Romania	High	100%	High	No	Yes	Yes	
Scotland	High	72%	High	No	Yes	Yes	The percentage is probably higher as this is limited to the Digital Screening Service in the previous 15 months only but other sources are in the dataset. Longer time frames for all data sources are also possible.
Slovenia	Medium	80%	Medium	No	Yes	Yes	
Sweden	High	80%	High	No	Yes	Yes	

Commentary: There are reasonable levels of consistency and completeness, although the quality of this information is not reported as ‘high’ across several partners. These caveats should be reported alongside any outputs.

Validity: Medium

6.22 Retinopathy Status

Definition: No Diabetic retinopathy, Background diabetic retinopathy or Referable Retinopathy (Pre-Proliferative Retinopathy / Proliferative Retinopathy)

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	70%	High	Yes	Yes	No	Field value is calculated using data for retinopathy status either for left eye or for right eye
Belgium	Not Recorded	0%	Not Recorded	No	No	No	
Croatia	Medium	98%	Medium	No	Yes	Yes	Retinopathy is defined as YES and NO; if YES then optional fields are 1=Nonproliferative, 2=Pre-proliferative and 3=Proliferative. Percentage in Data completeness is defined as percentage of retinopathy status in those who had an ophtalmologic examination in last 12 months. Fields are defined as D (right) and L (left); data completeness value is mean of those two values.
Cyprus	Medium	80%	Medium	Yes	Yes	Yes	
Germany	High	70%	High	Yes	Yes	No	Field value is calculated using data for retinopathy status either for left eye or for right eye
Hungary	Not Recorded	0%	Not Recorded	No	No	No	

Ireland	Low	8%	Medium	No	Yes	Yes	We record details for both right and left eyes. Data needs to be mapped. Not consistently recorded. Generally only positive findings recorded, this may impact data completeness.
Italy	Not Recorded	0%	Not Recorded	No	No	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	80%	High	No	Yes	Yes	
Norway	Low	50%	Low	No	Yes	Yes	We have: 1. No rethinopathy, 2. No lasertreated rethinopathy, 3. Lasertreated retinopathy, 4. Unknown
Romania	High	100%	High	No	Yes	Yes	
Scotland	High	72%	High	No	Yes	Yes	
Slovenia	Medium	80%	Medium	Yes	Yes	No	
Sweden	High	90%	High	No	Yes	Yes	

Commentary: Not recorded by three partners supplying data meaning it immediately has ‘Medium Validity’. General issues regarding local data recording can be resolved by mapping. As this is an ‘overall’ retinopathy status, this must be reported based on the status of the ‘worst’ eye.

Validity: Medium

6.23 Maculopathy

Definition: 1 = No Maculopathy 2 = Referable Maculopathy

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	60%	High	Yes	Yes	No	Field value is yes if either a maculopathy exists on the left or on the right eye
Belgium	Not Recorded	0%	Not Recorded	No	No	No	
Croatia	Medium	82%	High	No	Yes	Yes	Data completeness percentage is defined as Number with Status of Maculopathy/Number of those who had an opthalm exam in last 12 months. Fields are defined as D (right) and L (left); data completeness value is mean of those two values.
Cyprus	High	80%	Medium	Yes	Yes	Yes	
Germany	High	60%	High	Yes	Yes	No	Field value is yes if either a maculopathy exists on the left or on the right eye
Hungary	Not Recorded	0%	Not Recorded	No	No	No	
Ireland	Low	8%	Medium	No	Yes	Yes	We record details for both right and left eyes in greater detail. Data needs to be mapped. Not consistently recorded. Generally only positive findings recorded, this may impact data completeness.
Italy	Not Recorded	0%	Not Recorded	No	No	No	

Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	80%	High	No	Yes	Yes	
Norway	Not Recorded	0%	Not Recorded	No	No	No	
Romania	High	100%	High	No	Yes	Yes	
Scotland	High	72%	High	No	Yes	Yes	
Slovenia	Not Recorded	0%	Not Recorded	No	No	No	Since we work with children we rarely have late complications
Sweden	High	85%	High	No	Yes	Yes	

Commentary: Not well recorded across all partners with a very low percentage reported by Ireland.

Validity: Low

6.24 Foot Examination

Definition: 1 = Yes - Foot Examination Performed 2 = No - Year of Foot Examination field is NULL or contains invalid numeric data

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	Medium	80%	High	Yes	Yes	No	FQSD-Dataset only provides information of foot examinations performed in the last 12 months
Belgium	Medium	100%	Medium	No	Yes	Yes	I only know whether a foot examination was carried out during the data collection year, yes or no. It is not stored as the year when it was carried out.
Croatia	Low	17%	Medium	No	Yes	Yes	Field is defined as Foot exam in last 12 months with YES and NO. If YES then various subquestions are available with YES and NO as possible answers.
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	Medium	80%	High	Yes	Yes	No	FQSD-Dataset only provides information of foot examinations performed in the last 12 months
Hungary	Medium	95%	Medium	No	Yes	Yes	
Ireland	High	95%	Medium	No	Yes	Yes	Foot examination carried out at every clinic visit.
Italy	Not Recorded	0%	Not Recorded	No	No	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	80%	High	No	Yes	Yes	

Norway	Medium	50%	Medium	No	Yes	Yes	
Romania	High	60%	High	No	Yes	Yes	
Scotland	High	72%	High	No	Yes	Yes	
Slovenia	Not Recorded	0%	Not Recorded	No	No	No	Since we work with children we rarely have late complications
Sweden	High	80%	High	No	Yes	Yes	

Commentary: Although some partners report 'Medium' consistency with the definitions, the issues of concern are not believed to impact on the ability to report consistently, with mapping available when necessary.

Validity: High

6.25 Foot Pulses

Definition:

Present: Foot pulses should be recorded as present if either one or both of the two major arteries (dorsalis pedis and posterior tibial) of the foot are felt upon physical palpation. The presence of pulses by Doppler ankle pressure should be interpreted with caution since normal readings may be recorded in the presence of medial arterial calcification and could be misleading.
Absent: Foot Pulses Absent

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	70%	High	Yes	Yes	No	
Belgium	High	88%	High	No	Yes	Yes	
Croatia	Medium	94%	High	No	Yes	Yes	Percentage is defined as Number of Puls status available/number of those who had Foot Exam in last 12 months. Fields are defined as D (right) and L (left); data completeness value is mean of those two values.
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	High	70%	High	Yes	Yes	No	
Hungary	Medium	70%	Medium	Yes	Yes	No	
Ireland	High	95%	Medium	No	Yes	Yes	We record details for both right and left feet. Data needs to be mapped. Not consistently recorded.
Italy	Not Recorded	0%	Not Recorded	No	No	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	90%	High	No	Yes	Yes	

Norway	Medium	40%	Medium	No	Yes	Yes	We have: 1. Yes, both feet, 2. Yes, right foot, 3. Yes, left foot, 4 Foot pulses absent, 5. None examination done
Romania	High	60%	High	No	Yes	Yes	
Scotland	High	82%	High	No	Yes	Yes	
Slovenia	Not Recorded	0%	Not Recorded	No	No	No	Since we work with children we rarely have late complications
Sweden	Not Recorded	0%	Not Recorded	No	No	No	

Commentary: Foot pulse data is not recorded by three active partners, leading to a reduction in Validity. Mappings are available for areas commented. Overall foot pulses status must be based on the state of the 'worst' foot when left and right conflict.

Validity: Medium

6.26 Foot Sensation

Definition:

Normal: Normal foot sensation

Abnormal: Foot Sensation can be considered abnormal if monofilament and/or vibration sensation are impaired as defined below.

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	70%	High	Yes	Yes	No	
Belgium	High	81%	High	No	Yes	Yes	
Croatia	Medium	82%	Medium	No	Yes	Yes	Currently there are fields for normal needle/monofilament sensation, and vibration sensation for both legs seaparately. Fields are defined as D (right) and L (left); data completeness value is mean of these four values. Percentage is defined with denominator being patients who had their feet examined in last 12 months.
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	High	70%	High	Yes	Yes	No	
Hungary	Medium	95%	Medium	No	Yes	Yes	
Ireland	Medium	95%	Medium	No	Yes	Yes	We record details for both right and left feet. Data needs to be mapped. Not consistently recorded.
Italy	Not Recorded	0%	Not Recorded	No	No	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	

Malta	High	90%	High	No	Yes	Yes	
Norway	Medium	50%	Medium	No	Yes	Yes	We have: 1. Yes, both feet normal, 2. Yes, right foot normal, 3. Yes, left foot normal, 4 Abnormal footsensation, 5. None examination done
Romania	High	60%	High	No	Yes	Yes	
Scotland	High	82%	High	No	Yes	Yes	This is often derived from other foot assessment values
Slovenia	Not Recorded	0%	Not Recorded	No	No	No	Since we work with children we rarely have late complications
Sweden	Not Recorded	0%	Not Recorded	No	No	No	

Commentary: Foot sensation data is not recorded by three active partners, leading to a reduction in Validity. Mappings are available for areas commented. Overall foot sensation status must be based on the state of the 'worst' foot when left and right conflict.

Validity: Medium

6.27 End Stage Renal Failure

Definition: Year that either serum creatinine was chronically greater than 300umol/l (i.e. >300 umol/l on two occasions three months apart) or the patient was placed on permanent dialysis or received a renal transplant.

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	Not Recorded	0%	Not Recorded	No	No	No	
Belgium	Medium	95%	Medium	No	Yes	Yes	I only know whether a patient has ESRF, yes or no. It is not stored as the year when it first occurred.
Croatia	Low	51%	Medium	No	Yes	Yes	Currently there is a field with Terminal stage of renal disease (Yes or No); If Yes then - Within last 12 months (Yes or No). P.S. The title should be ESRF (End Stage Renal Failure).
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	Not Recorded	0%	Not Recorded	No	No	No	
Hungary	Not Recorded	0%	Not Recorded	No	No	No	
Ireland	Medium	95%	Medium	No	Yes	Yes	Information not recorded in a quantifiable manner on our system. Data is available from another source, only contains those being treated for renal conditions in our hospital.
Italy	Not Recorded	0%	Not Recorded	No	No	No	

Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	90%	High	No	Yes	Yes	
Norway	Not Recorded	0%	Not Recorded	No	No	No	We have a data item that contains whether the patient gets dialysis or not
Romania	High	100%	High	No	Yes	Yes	
Scotland	High	86%	High	No	Yes	Yes	The percentage value here is just a guess as it is not possible to determine how many we have missing?
Slovenia	Not Recorded	0%	Not Recorded	No	No	No	Since we work with children we rarely have late complications
Sweden	Not Recorded	0%	Not Recorded	No	No	No	

Commentary: Many partners do not record end stage renal failure, although those who do record it consistently or in a format that can be mapped.

Validity: Low

6.28 Renal Dialysis

Definition: 1 = Yes: Year of Dialysis field contains valid year number 0 = No: Year of Dialysis field is NULL or contains invalid numeric data

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	Not Recorded	0%	Not Recorded	No	No	No	
Belgium	Not Recorded	0%	Not Recorded	No	No	No	
Croatia	Not Recorded	0%	Not Recorded	No	No	No	
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	Not Recorded	0%	Not Recorded	No	No	No	
Hungary	Not Recorded	0%	Not Recorded	No	No	No	
Ireland	Medium	95%	Medium	No	Yes	Yes	Information not recorded in a quantifiable manner on our system. Data is available from another source, only contains those being treated for renal conditions in our hospital.
Italy	Not Recorded	0%	Not Recorded	No	No	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	

Malta	Not Recorded	0%	Not Recorded	No	No	No	In our database this is recorded as Yes if the patient is either on dialysis or has had a transplant. We are taking steps to split these.
Norway	Medium	70%	Medium	No	Yes	Yes	
Romania	High	40%	High	No	Yes	Yes	
Scotland	High	50%	High	No	Yes	Yes	The percentage value here is just a guess as it is not possible to determine how many we have missing?
Slovenia	Not Recorded	0%	Not Recorded	No	No	No	Since we work with children we rarely have late complications
Sweden	Not Recorded	0%	Not Recorded	No	No	No	

Commentary: Renal dialysis is not recorded in the partner datasets although those that do record it do so in a way that may lead to reasonable comparisons.

Validity: Low

6.29 Renal Transplant

Definition: Transplantation (Year) 1 = Yes: Year of Transplant field contains valid year number 0 = No: Year of Transplant field is NULL or contains invalid numeric data

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	Not Recorded	0%	Not Recorded	No	No	No	
Belgium	Not Recorded	0%	Not Recorded	No	No	No	
Croatia	Not Recorded	0%	Not Recorded	No	No	No	
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	Not Recorded	0%	Not Recorded	No	No	No	
Hungary	Not Recorded	0%	Not Recorded	No	No	No	
Ireland	Medium	95%	Medium	No	Yes	Yes	Information not recorded in a quantifiable manner on our system. Data is available from another source, only contains those being treated for renal conditions in our hospital.
Italy	Not Recorded	0%	Not Recorded	No	No	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	

Malta	Not Recorded	0%	Not Recorded	No	No	No	In our database this is recorded as Yes if the patient is either on dialysis or has had a transplant. We are taking steps to split these.
Norway	Medium	70%	Medium	No	No	No	
Romania	Not Recorded	0%	Not Recorded	No	No	No	
Scotland	High	50%	High	No	Yes	Yes	Again, percentage is really arbitrary as there is no way of determining what we don't have at this stage.
Slovenia	Not Recorded	0%	Not Recorded	No	No	No	Since we work with children we rarely have late complications
Sweden	Not Recorded	0%	Not Recorded	No	No	No	

Commentary: Only four partners record any kind of renal transplant data making cross-Europe comparison incomplete.

Validity: Low

6.30 Stroke

Definition: Cerebrovascular accident (stroke) is defined as rapidly developing signs of focal (and/or global) disturbance of cerebral function lasting more than 24 hours or leading to death with no apparent cause other than vascular origin.

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	Medium	25%	High	Yes	Yes	No	encephalomalacia or bleedings due to hypertension (St. Vincent Declaration)
Belgium	Medium	99%	Medium	No	Yes	Yes	I only know whether a patient has had a stroke, yes or no. It is not stored as the year when the patient first suffered from stroke.
Croatia	Medium	52%	Medium	No	Yes	Yes	Field Stroke has options YES and NO; If YES then Within last 12 Months YES or NO.
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	Medium	25%	High	Yes	Yes	No	encephalomalacia or bleedings due to hypertension (St. Vincent Declaration)
Hungary	High	90%	High	Yes	Yes	No	
Ireland	Low	95%	Low	No	Yes	Yes	Information is not recorded in a consistent manner and therefore may be unquantifiable.
Italy	Not Recorded	0%	Not Recorded	No	No	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	90%	High	No	Yes	Yes	
Norway	Medium	70%	High	No	Yes	Yes	
Romania	High	40%	High	No	Yes	Yes	
Scotland	High	50%	High	No	Yes	Yes	Arbitrary percentage value

Slovenia	Not Recorded	0%	Not Recorded	No	No	No	Since we work with children we rarely have late complications
Sweden	High	80%	High	No	Yes	Yes	

Commentary: Stroke results are not recorded by some partners and there are reports of slight deviations in clinical definition. Despite this, worthwhile comparisons are still expected.

Validity: Medium

6.31 Active Foot Ulcer

Definition: Ulcer is defined as any break in the epithelium greater than a crack below the level of the malleoli. It is required as an indicator of possible risk of future amputation.

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	Medium	55%	High	Yes	Yes	No	An active foot ulcer is defined as "field contains valid year". That's why we use the field 'activeFootUlcer' as well as the field 'curedFootUlcer' to calculate ULCER = 1 [YES]
Belgium	Medium	96%	Medium	No	Yes	Yes	I only know whether a patient has had an ulcer before, yes or no. It is not stored as the year when the patient first had an ulcer.
Croatia	Medium	60%	Medium	No	Yes	Yes	
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	Medium	55%	High	Yes	Yes	No	An active foot ulcer is defined as "field contains valid year". That's why we use the field 'activeFootUlcer' as well as the field 'curedFootUlcer' to calculate ULCER = 1 [YES]
Hungary	Medium	95%	Medium	No	Yes	Yes	
Ireland	Low	3%	Medium	No	Yes	Yes	We record details for both right and left feet. Data needs to be mapped. Not consistently recorded. Generally only positive findings recorded, this may impact data completeness.
Italy	Not Recorded	0%	Not Recorded	No	No	No	

Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	90%	High	No	Yes	Yes	
Norway	Medium	70%	Medium	No	No	No	
Romania	High	40%	High	No	Yes	Yes	
Scotland	Medium	70%	Medium	No	Yes	Yes	Arbitrary percentage as data inclusion from clinical systems is not vetted.
Slovenia	Not Recorded	0%	Not Recorded	No	No	No	Since we work with children we rarely have late complications
Sweden	High	85%	High	No	Yes	Yes	

Commentary: Recording of ‘active’ foot ulcers is not routinely possible based on local data collection methods. Consideration to be made to revise this data item as ‘History of Foot Ulcer’ so that reporting can be made based on those patients who have ever had a foot ulcer.

Validity: Medium

6.32 Myocardial Infarction

Definition: Myocardial infarction proven by ECG, cardiac enzymes or heart perfusion scan or other reliable methodology, but not on clinical features alone.

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	85%	High	Yes	Yes	No	1 if St. Vincent Goal Myocardial Infarct is yes
Belgium	Medium	99%	Medium	No	Yes	Yes	I only know whether a patient has had a MI before, yes or no. It is not stored as the year when the patient first suffered from a MI.
Croatia	Medium	52%	Medium	No	Yes	Yes	Field MI/CABG/Angioplasty has options YES and NO; If YES then Within last 12 Months YES or NO.
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	High	85%	High	Yes	Yes	No	1 if St. Vincent Goal Myocardial Infarct is yes
Hungary	Medium	95%	Medium	No	Yes	Yes	
Ireland	Low	95%	Low	No	Yes	Yes	Information is not recorded in a consistent manner and therefore may be unquantifiable.
Italy	Not Recorded	0%	Not Recorded	No	No	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	90%	High	No	Yes	Yes	
Norway	Medium	70%	High	No	No	No	
Romania	High	60%	High	No	Yes	Yes	

Scotland	High	50%	High	No	No	No	Arbitrary percentage value
Slovenia	Not Recorded	0%	Not Recorded	No	No	No	Since we work with children we rarely have late complications
Sweden	High	80%	High	No	Yes	Yes	

Commentary: Issues recorded with recording methods although other problems can be resolved by appropriate mappings.

Validity: Medium

6.33 Laser

Definition: Record of each episode of laser treatment on eye

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	70%	High	Yes	Yes	No	
Belgium	Medium	88%	Medium	No	Yes	Yes	I only know whether a patient has had a laser treatment before, yes or no. It is not stored as the year when the laser treatment was carried out.
Croatia	Medium	89%	Medium	No	Yes	Yes	Field Photocoagulation has options YES and NO for both eyes (R and L) within eye examination. Field EYE EXAMINATION WITHIN LAST 12 MONTHS must be marked as YES in order to fill this field. Data completeness is shown as denominator being number of patients with eye exam in last 12 months and is mean of values for right and left eye.
Cyprus	Not Recorded	0%	Not Recorded	No	No	No	
Germany	High	70%	High	Yes	Yes	No	
Hungary	Medium	90%	Medium	No	Yes	Yes	
Ireland	Not Recorded	0%	Not Recorded	No	No	No	Rarely recorded on our database.
Italy	Not Recorded	0%	Not Recorded	No	No	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	

Malta	Medium	70%	Medium	No	Yes	Yes	At present our database records whether the patient has had Laser treatment or not. The date is not recorded
Norway	Not Recorded	0%	Not Recorded	No	No	No	
Romania	High	100%	High	No	Yes	Yes	
Scotland	High	85%	High	No	Yes	Yes	Not routinely recorded.
Slovenia	Not Recorded	0%	Not Recorded	No	No	No	Since we work with children we rarely have late complications
Sweden	Not Recorded	0%	Not Recorded	No	No	No	

Commentary: Generally evidence of laser therapy is poorly recorded across EUBIROD partners.

Validity: Low

6.34 Hypertension

Definition: 1 = Yes: Hypertension field contains valid year number 0 = No: Hypertension field is NULL or contains invalid numeric data

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	Medium	65%	High	Yes	Yes	No	FQSD dataset doesn't have a field containing status of hypertension. Hypertension is approximated using fields: -> Patient gets treatment against hypertension -> Systolic blood pressure is over 140 AND Diastolic blood pressure is over 90
Belgium	Not Recorded	0%	Not Recorded	No	No	No	
Croatia	Not Recorded	0%	Not Recorded	No	No	No	There is no field for hypertension per se, however there is a field for taking antihypertensive medication.
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	Medium	65%	High	Yes	Yes	No	FQSD dataset doesn't have a field containing status of hypertension. Hypertension is approximated using fields: -> Patient gets treatment against hypertension -> Systolic blood pressure is over 140 AND Diastolic blood pressure is over 90
Hungary	Not Recorded	0%	Not Recorded	No	No	No	

Ireland	Low	95%	Low	No	Yes	Yes	Information is not recorded in a consistent manner and therefore may be unquantifiable.
Italy	Not Recorded	0%	Not Recorded	No	No	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	90%	High	No	Yes	Yes	
Norway	Not Recorded	0%	Not Recorded	No	No	No	
Romania	High	100%	High	No	Yes	Yes	
Scotland	Low	5%	Low	No	No	No	Hypertension may be derived for BP values over time
Slovenia	Medium	80%	Medium	No	Yes	Yes	
Sweden	High	85%	High	No	Yes	Yes	

Commentary: Although it would appear that hypertension is poorly recorded, consideration must be given to mappings from blood pressure records. Where possible, this is likely to yield comparable report outputs.

Validity: Medium

6.35 Blindness

Definition: Permanent blindness is defined as permanent visual acuity corrected (i.e. wearing corrective lenses) of less than 3/60 (i.e. CF, HM, PL or NPL) in the better eye.

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	Medium	99%	High	Yes	Yes	No	For the FQSD-system a patient is blind if he/she gets national sponsorship for blindness. National sponsorship will be granted if: -> visus of 1/60 or below without deficiencies in the field of sight -> visus of 2/60 or below in combination with Quadrantanopia -> visus of 4/60 or below in combination with Hemianopsia -> visus of 6/60 or below in combination with tubular deficiencies in the field of sight If a patient doesn't get national sponsorship due to any reasons although one of the criterion mentioned above is fulfilled, the value of field 'Blindness' in FQSD dataset is recorded as negative
Belgium	Medium	94%	Medium	No	Yes	Yes	I only know whether a patient is blind, yes or no. It is not stored as the year when the patient became blind.
Croatia	Medium	56%	Medium	No	Yes	Yes	Field Blindness has options YES and NO; If YES then Within last 12 Months YES or NO (data completeness is drawn from this field). Also, in

Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	Medium	99%	High	Yes	Yes	No	For the FQSD-system a patient is blind if he/she gets national sponsorship for blindness. National sponsorship will be granted if: -> visus of 1/60 or below without deficiencies in the field of sight -> visus of 2/60 or below in combination with Quadrantanopia -> visus of 4/60 or below in combination with Hemianopsia -> visus of 6/60 or below in combination with tubular deficiencies in the field of sight If a patient doesn't get national sponsorship due to any reasons although one of the criterion mentioned above is fulfilled, the value of field 'Blindness' in FQSD dataset is recorded as negative
Hungary	Medium	95%	Medium	No	Yes	Yes	
Ireland	Low	95%	Low	No	Yes	Yes	We record details for both right and left eyes. Data may be unmappable. Not consistently recorded.
Italy	Not Recorded	0%	Not Recorded	No	No	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	90%	High	No	Yes	Yes	
Norway	Medium	70%	High	No	Yes	Yes	
Romania	High	100%	High	No	Yes	Yes	

Scotland	High	95%	High	No	Yes	Yes	
Slovenia	Not Recorded	0%	Not Recorded	No	No	No	Since we work with children we rarely have late complications
Sweden	Not Recorded	0%	Not Recorded	No	No	No	

Commentary: Although there are variations in local definitions of blindness, these can be explained alongside the data presented in case of variation.

Validity: Medium

6.36 Amputation

Definition: Removal of forefoot or part of the lower limb 1 = Yes: Amputation field contains valid year number 0 = No : Amputation field is NULL or contains invalid numeric data

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	85%	High	Yes	Yes	No	
Belgium	Medium	98%	Medium	No	Yes	Yes	I only know whether a patient had an amputation before, yes or no. It is not stored as the year when the amputation was carried out.
Croatia	Medium	51%	Medium	No	Yes	Yes	Fields Amputation above ankle and Amputation below ankle have options YES and NO; If YES then Within last 12 Months YES or NO (data completeness is mean of these two values).
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	High	85%	High	Yes	Yes	No	
Hungary	Medium	90%	Medium	No	Yes	Yes	
Ireland	Low	2%	Medium	No	Yes	Yes	We record details for both right and left feet. Data needs to be mapped. Not consistently recorded. Generally only positive findings recorded, this may impact data completeness.
Italy	Not Recorded	0%	Not Recorded	No	No	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	

Malta	High	90%	High	No	Yes	Yes	
Norway	Medium	70%	Medium	No	Yes	Yes	
Romania	High	40%	High	No	Yes	Yes	
Scotland	High	95%	High	No	Yes	Yes	
Slovenia	Not Recorded	0%	Not Recorded	No	No	No	Since we work with children we rarely have late complications
Sweden	High	85%	High	No	Yes	Yes	

Commentary: Amputation data appears to be reasonably consistent amongst the partners who record this data. Where comments have been made, mappings can resolve the conversion to EUBIROD standards.

Validity: Medium

6.37 Antihypertensive Medication

Definition: 1 = Yes: Date of record of treatment using antihypertensive drugs is valid 0= No: date of record of treatment using antihypertensive drugs is NULL or contains invalid data

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	65%	High	Yes	Yes	No	
Belgium	Medium	97%	Medium	No	Yes	Yes	I only know whether a patient was treated for hypertension during the data collection year, yes or no. It is not stored as the date of treatment.
Croatia	Low	31%	Medium	No	Yes	Yes	Field Antihypertensive treatment has options YES and NO.
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	High	65%	High	Yes	Yes	No	
Hungary	Medium	90%	Medium	No	Yes	Yes	
Ireland	Low	95%	Low	No	Yes	Yes	Information is not recorded in a consistent manner and therefore may be unquantifiable.
Italy	Not Recorded	0%	Not Recorded	No	No	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	90%	High	No	Yes	Yes	
Norway	Medium	70%	High	No	Yes	Yes	
Romania	High	60%	High	No	Yes	Yes	
Scotland	High	90%	High	No	Yes	Yes	May be derived from prescribing data
Slovenia	Medium	80%	Medium	No	Yes	Yes	

Sweden	High	90%	High	No	Yes	Yes

Commentary: Reasonably comparable data item based on the results reported. Again, data mappings can be used to resolve data issues.

Validity: Medium

6.38 Hypoglycaemic Drug Therapy

Definition: Date of treatment is valid 1 = Insulin Only 2 = Tablet Only 3 = Insulin and Tablets 4 = None (Diet Only)

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	60%	High	Yes	Yes	No	
Belgium	Medium	99%	Medium	No	Yes	Yes	I only know whether a patient was treated with insulin or tablets during the data collection year, yes or no. It is not stored as "the date of treatment".
Croatia	High	78%	Medium	No	Yes	Yes	This section begins with question Diet only (If YES no further choices are available), If NO theChoice is between different classes of Hypoglycemic drug therapy, number of insulin injections per day, Insulin Pump and other forms of diabetes treatment.
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	High	60%	High	Yes	Yes	No	
Hungary	Medium	90%	Medium	No	Yes	Yes	
Ireland	High	100%	Medium	No	Yes	Yes	Recorded in separate fields in our database. Data mapping will be required.
Italy	Low	10%	Low	No	Yes	Yes	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	99%	High	No	Yes	Yes	At present this is recorded in our database but is not being captured properly by the BIRO database. We need to correct this at our end.

Norway	Medium	70%	High	No	Yes	Yes	
Romania	High	100%	High	No	Yes	Yes	
Scotland	High	90%	High	No	Yes	Yes	Can be derived from drug data
Slovenia	Not Recorded	0%	Not Recorded	No	No	No	We have only patients with T1D and are in all cases using just insulin, in the register the insulin fabric name for each patient is recorded
Sweden	High	90%	High	No	Yes	Yes	

Commentary: General levels of consistency with the dataset definition have been reported which should lead to acceptable reporting.

Validity: Medium

6.39 Oral Drug Therapy

Definition: Date of treatment is valid 1 = Sulphonylureas 2 = Biguanides 3 = Glucosidase Inhibitors 4 = Glitazones 5 = Glinides

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	Medium	25%	High	Yes	Yes	No	Only oral drugs of the classes Sulphonylureas, Bigunaides and Glucosidase are recorded in the dataset. For every dataset not being either 1, 2 or 3 BIRO-item ORAL_THERAPY will be recorded as NULL
Belgium	Medium	99%	Medium	No	Yes	Yes	Up to now I am not using these data, because I don't know how to categorise patients taking for example both Biguanides and Sulphonylureas.
Croatia	High	67%	High	No	Yes	Yes	Data completeness is average of these five fields (all have options yes and no). There is also the field Diabetes Oral Therapy Since.
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	Medium	25%	High	Yes	Yes	No	Only oral drugs of the classes Sulphonylureas, Bigunaides and Glucosidase are recorded in the dataset. For every dataset not being either 1, 2 or 3 BIRO-item ORAL_THERAPY will be recorded as NULL
Hungary	Medium	90%	Medium	No	Yes	Yes	

Ireland	Low	100%	Medium	No	Yes	Yes	Not cuurently recorded in our database using the categories as listed in 'clinical definition'. Work required but data should be available.
Italy	Low	10%	Low	No	Yes	Yes	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	99%	High	No	Yes	Yes	At present this is recorded in our database but is not being captured properly by the BIRO database. We need to correct this at our end.
Norway	Low	70%	Low	No	Yes	Yes	We have: 1. sulfphonylureas, 2. Biguanides 3. Glitazones 4. Inkretines, 5. Others (Novonorm, starlix, Glucobay)
Romania	High	100%	High	No	Yes	Yes	
Scotland	Medium	90%	High	No	Yes	Yes	Therapy type may be derived from actual drugs
Slovenia	Not Recorded	0%	Not Recorded	No	No	No	No patients with T2D are in the register, they will be added this year (we have only 20 to 25 patients with T2D)
Sweden	High	90%	High	No	Yes	Yes	

Commentary: Reasonable levels of consistency with the dataset definition have been reported which should lead to acceptable reporting. Multiple drug therapy records are possible with the current data schema to capture data on those patients taking more than one type of therapy. A decision has been made to split these drug therapies into individual data items in their own right.

Validity: Medium

6.40 Pump Therapy

Definition: 1 = Yes: Date of record of treatment by insulin pump is valid 0 = No: Date of record of treatment by insulin pump is NULL or contains invalid date

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	85%	High	Yes	Yes	No	
Belgium	Not Recorded	0%	Not Recorded	No	No	No	
Croatia	Low	52%	Medium	No	Yes	Yes	Within part with treatment of diabetes there is a field for insulin pump treatment with options YES and NO.
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	High	85%	High	Yes	Yes	No	
Hungary	Not Recorded	0%	Not Recorded	No	No	No	
Ireland	High	95%	Medium	No	Yes	Yes	Limited number of patients. Data is available from alternative source.
Italy	Not Recorded	0%	Not Recorded	No	No	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	90%	High	No	Yes	Yes	Insulin Pump therapy is rarely used in Malta
Norway	Medium	80%	High	No	Yes	Yes	
Romania	High	80%	High	No	Yes	Yes	
Scotland	High	90%	Medium	No	Yes	Yes	Can be derived from prescribing data
Slovenia	High	95%	High	No	Yes	Yes	
Sweden	High	85%	High	No	Yes	Yes	

Commentary: Most partners record some form of pump therapy record with good levels of completeness.

Validity: Medium

6.41 Inhaled Therapy

Definition: 1 = Yes: Date of record of treatment by nasal therapy is valid 0 = No: Date of record of treatment by nasal therapy is NULL or contains invalid date

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	Not Recorded	0%	Not Recorded	No	No	No	
Belgium	Not Recorded	0%	Not Recorded	No	No	No	
Croatia	Not Recorded	0%	Not Recorded	No	No	No	
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	Not Recorded	0%	Not Recorded	No	No	No	
Hungary	Not Recorded	0%	Not Recorded	No	No	No	
Ireland	Not Recorded	0%	Not Recorded	No	No	No	Not Applicable: Inhaled therapy is not used in our clinic.
Italy	Not Recorded	0%	Not Recorded	No	No	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	Not Recorded	0%	Not Recorded	No	No	No	Not used in Malta
Norway	Not Recorded	0%	Not Recorded	No	No	No	

Romania	Not Recorded	0%	Not Recorded	No	No	No	
Scotland	High	100%	High	No	Yes	Yes	Can be derived from prescribing data
Slovenia	Not Recorded	0%	Not Recorded	No	No	No	No inhaled therapy is used
Sweden	Not Recorded	0%	Not Recorded	No	No	No	

Commentary: Recording of this data item is almost non-existent. It is recommended that this data item and associated indicators are retired until it is possible to capture this information.

Validity: Low

6.42 Average Injections

Definition: Average number of insulin injections recorded per day

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	80%	High	Yes	Yes	No	
Belgium	High	99%	High	No	Yes	Yes	
Croatia	Medium	33%	Medium	No	Yes	Yes	The field Number of insulin injections per day does not allow decimal numbers to be entered. The data completeness percentage is somewhat low because patients who are not on insulin therapy sometimes have this field left empty, as though it wasn`t filled.
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	High	80%	High	Yes	Yes	No	
Hungary	Medium	90%	Medium	No	Yes	Yes	
Ireland	Low	95%	Low	No	Yes	Yes	Insulin injections recorded individually and in notes. Not quantifiable.
Italy	Not Recorded	0%	Not Recorded	No	No	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	90%	High	No	Yes	Yes	At present this is recorded in our database but is not being captured properly by the BIRO database. We need to correct this at our end.
Norway	Not Recorded	0%	Not Recorded	No	No	No	

Romania	High	100%	High	No	Yes	Yes	
Scotland	Low	90%	Medium	No	Yes	Yes	Not even routinely recorded
Slovenia	Not Recorded	0%	Not Recorded	No	No	No	More then 80% of patients are using pumps,. the rest on 4 to 6 injections all
Sweden	Not Recorded	0%	Not Recorded	No	No	No	

Commentary: A reasonable level of consistent comparison will be possible using this data item. Borderline Medium/Low validity data item which may change as further clarification is requested.

Validity: Medium

6.43 Self Monitoring

Definition: 1 = Urine: Self monitoring refers to use of reagent strips for monitoring blood or urinary glucose (at least 1 test per week) 2 = Blood Glucose 3 = Both

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	65%	High	Yes	Yes	No	
Belgium	Medium	100%	Medium	No	Yes	Yes	We do not have data on SM urine glucose, but that is because normally in Belgium this is not used any longer
Croatia	High	68%	Medium	No	Yes	Yes	There is a field for selfmonitoring (YES or NO); If YES then field for Selfmonitoring blood glucose (times per week) and Selfmonitoring urine glucose (times per week). Data completeness is shown for selfmonitoring field.
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	High	65%	High	Yes	Yes	No	
Hungary	Medium	95%	Medium	No	Yes	Yes	
Ireland	Low	95%	Low	No	Yes	Yes	Data stored in separate fields, not recorded consistently. May be unmappable.
Italy	Not Recorded	0%	Not Recorded	No	No	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	90%	High	No	Yes	Yes	
Norway	Not Recorded	0%	Not Recorded	No	No	No	We just have self-monitoring in blood glucose

Romania	High	60%	High	No	Yes	Yes	
Scotland	Low	0%	Low	No	No	No	Strip uptake can be derived from prescribing data but actual testing patterns cannot.
Slovenia	Not Recorded	0%	Not Recorded	No	No	No	All patients are controlling urine, so no need for special record in the registry
Sweden	Not Recorded	0%	Not Recorded	No	No	No	

Commentary: Most partners record some form of self-monitoring data although completeness is variable.

Validity: Medium

6.44 Diabetes Specific Education

Definition: This is very difficult to define and has not been defined until now. SDCD holds fields for advice on diet and pregnancy only. DiabCare holds many educational fields: general advice, healthy eating, hypoglycaemia, etc.

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	Medium	50%	High	Yes	Yes	No	FQSD dataset contains field for education concerning: Nutrition, hypoglycaemia, diabetic foot syndrome, therapy, risk factors, diabetic complications, self-monitoring or member of a support-group. If any of the educational fields mentioned above is checked as true BIRO-field EDUCATION is 1
Belgium	Not Recorded	0%	Not Recorded	No	No	No	
Croatia	Medium	43%	Medium	No	Yes	Yes	There are several fields associated with diabetes specific education, all with YES and NO options, namely: Healthy diet, Feet care, Complications, Selfmonitoring, Hypoglycaemia, Autonomous treatment changes, Member of Diabetic associations. Data completeness is average of these 7 values.
Cyprus	High	100%	High	Yes	Yes	Yes	There is no stractured education as yest in cyprus. However, the DSN teaches according to an agreed caricullum and according to individual needs of patient.

Germany	Medium	50%	High	Yes	Yes	No	FQSD dataset contains field for education concerning: Nutrition, hypoglycaemia, diabetic foot syndrome, therapy, risk factors, diabetic complications, self-monitoring or member of a support-group. If any of the educational fields mentioned above is checked as true BIRO-field EDUCATION is 1
Hungary	Not Recorded	0%	Not Recorded	No	No	No	
Ireland	High	100%	Medium	Yes	Yes	No	Diabetes education is mandatory in our service. Mapping required.
Italy	Not Recorded	0%	Not Recorded	No	No	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	Low	20%	Low	No	Yes	Yes	We are not clear how to deal with this issue at present.
Norway	Medium	70%	High	No	Yes	Yes	
Romania	High	60%	High	No	Yes	Yes	
Scotland	High	90%	High	No	Yes	Yes	
Slovenia	Not Recorded	0%	Not Recorded	No	No	No	All patients are receiving specific education at the T1D diagnose - 5 days, at pump start - 3 days
Sweden	Not Recorded	0%	Not Recorded	No	No	No	No good standard to extract these data

Commentary: Regrettably, the definition associated with this data item is clearly not a valid definition at all and the field can be interpreted as either healthcare advice discussed during a consultation or passed as some form of patient-literature. Within these

categories, it must be specified which topics or accumulated topics meet the remit of ‘Diabetes-Specific Education’. From the comments provided by partners, it would appear to be possible to capture education on a variety of topics so it is likely that data item can be clarified and meaningful data captured.

In its present form, this data item cannot be classified as anything other than having Low Validity. Further discussion is necessary.

Validity: Low

6.45 LDL Cholesterol

Definition: Serum LDL cholesterol can be either fasted or unfasted

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	60%	High	Yes	Yes	No	
Belgium	Low	52%	High	No	Yes	Yes	We do not ask LDL-cholesterol as such in the data collection. We calculate LDL-cholesterol using the Friedewald formula. So since about half of the patients were not in a fasting status, we can calculate LDL-cholesterol for only about 50%.
Croatia	Medium	56%	High	No	Yes	Yes	Usually measured while fasted.
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	High	60%	High	Yes	Yes	No	
Hungary	High	80%	High	Yes	Yes	No	
Ireland	High	95%	High	No	Yes	Yes	Our system has a direct LIS interface with the hospital lab. Some tests completed outside of the hospital lab service will be missing.
Italy	Medium	16%	High	No	Yes	Yes	units: mg/dL
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	83%	High	No	Yes	Yes	NB. In fact most patients have their lab investigations performed at least once a year. At present our laboratory results are recorded into a separate database and have to be typed manually into the diabetes database. Hence the low percentage.

Norway	Medium	60%	High	No	Yes	Yes	
Romania	High	60%	High	No	Yes	Yes	
Scotland	High	94%	High	No	Yes	Yes	Was not a standard test in Tayside but has been recorded more frquently since 2005
Slovenia	Not Recorded	0%	Not Recorded	No	No	No	
Sweden	High	90%	High	No	Yes	Yes	

Commentary: Very high consistency has been reported between partners, although completeness is variable. Although some partners record all forms of cholesterol with units ‘mg/dL’, this is not problematic as a mapping can be performed.

Validity: High

6.46 Alcohol Status

Definition: Alcohol status at date of contact 1 = Current Drinker 2 = Non-Drinker 3 = Ex-Drinker

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	70%	High	Yes	Yes	No	FQSD doesn't capture data about Ex-Drinkers. Only NULL, 1, 2 are possible values
Belgium	Not Recorded	0%	Not Recorded	No	No	No	
Croatia	Low	73%	Medium	No	Yes	Yes	At present, alcohol consumption is defined only as YES=Current Drinker, and NO=Non-Drinker.
Cyprus	High	100%	High	Yes	Yes	Yes	
Germany	High	70%	High	Yes	Yes	No	FQSD doesn't capture data about Ex-Drinkers. Only NULL, 1, 2 are possible values
Hungary	Medium	80%	Medium	No	Yes	Yes	
Ireland	Not Recorded	0%	Not Recorded	No	No	No	
Italy	Low	0%	Low	No	No	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	90%	High	No	Yes	Yes	Please note that by current drinker we mean that patient has an alcohol problem
Norway	Not Recorded	0%	Not Recorded	No	No	No	
Romania	High	80%	High	No	Yes	Yes	

Scotland	Low	0%	Low	No	No	No	Not recorded in this way - we have indicators of alcohol problems. It may be possible to derive this from alcohol consumption values
Slovenia	Not Recorded	0%	Not Recorded	No	No	No	T1DM registry for children!
Sweden	Not Recorded	0%	Not Recorded	No	No	No	

Commentary: Similarly to ‘Alcohol Intake’, alcohol consumption status is not well recorded across all partners.

Validity: Low

6.47 Patient Enrolment in Disease Management Programme (DMP)

Definition: 1 = Yes Date of record of patient enrolment in structured Diabetes Disease Management Programme 0 = No Date of record of patient enrolment in structured Diabetes

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	Not Recorded	0%	Not Recorded	No	No	No	
Belgium	Not Recorded	0%	Not Recorded	No	No	No	
Croatia	Not Recorded	0%	Not Recorded	No	No	No	
Cyprus	Not Recorded	0%	Not Recorded	No	No	No	
Germany	Not Recorded	0%	Not Recorded	No	No	No	
Hungary	Not Recorded	0%	Not Recorded	No	No	No	
Ireland	Low	0%	Low	No	Yes	Yes	Not part of our clinical practice at present. New pilot scheme currently being set up.
Italy	Not Recorded	0%	Not Recorded	No	No	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	Not Recorded	0%	Not Recorded	No	No	No	
Norway	Not Recorded	0%	Not Recorded	No	No	No	

Romania	High	80%	High	No	Yes	Yes	
Scotland	High	90%	High	No	Yes	Yes	
Slovenia	Not Recorded	0%	Not Recorded	No	No	No	All patients are in DMP programme
Sweden	Not Recorded	0%	Not Recorded	No	No	No	No good standard to extract these data

Commentary: Only two partners capture data on disease management programmes at present. This is potentially a far better standard and definition than simply 'Diabetes Specific Education' but the definition should be widened to describe it as consisting of 'structured' education course or session covering multiple topics. These relevant topics can be specified and a minimum required number included.

Validity: Low

6.48 Activity Start Date

Definition: Date of commencement of current period of patient activity

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	High	95%	High	Yes	Yes	No	Due to the fact, that fqsd data is mainly collected in an outpatient area 75% of the datasets have the same value for AD_START_DATE and AD_END_DATE
Belgium	Not Recorded	0%	Not Recorded	No	No	No	I don't know what is meant by this
Croatia	Not Recorded	0%	Not Recorded	No	No	No	
Cyprus	Not Recorded	0%	Not Recorded	No	No	No	will now start recording above field
Germany	High	95%	High	Yes	Yes	No	Due to the fact, that fqsd data is mainly collected in an outpatient area 75% of the datasets have the same value for AD_START_DATE and AD_END_DATE
Hungary	Not Recorded	0%	Not Recorded	No	No	No	
Ireland	Low	100%	Low	No	Yes	Yes	Dates of clinic visits recorded. Possible to calculate activity intervals.
Italy	Not Recorded	0%	Not Recorded	No	No	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	Not Recorded	0%	Not Recorded	No	No	No	

Norway	Not Recorded	0%	Not Recorded	No	No	No	Difficult to understand the data item, what does "current period" mean?. We do register from the patients first enrty to the registry and longitudinally from there
Romania	High	60%	High	No	Yes	Yes	
Scotland	High	90%	High	No	Yes	Yes	I don't know what this means?
Slovenia	Not Recorded	0%	Not Recorded	No	No	No	
Sweden	Not Recorded	0%	Not Recorded	No	No	No	What do you mean by this one? Do you mean date for the last patient visit a GP?

Commentary: During data entry, there was clearly ambiguity about the concept of periods of patient activity. This was discussed and clarification given at the EUBIROD meeting in Rome, June 2010. During these discussions it became clear that most partners cannot provide accurate information on patient activity at present. 'Patient Activity Status' is detailed in the published BIRO Monograph (http://www.eubirod.eu/documents/downloads/BIRO_Monograph.pdf), however its definition will be full reiterated in the summary and discussion section later in this document.

Validity: Low

6.49 Activity Start Reason

Definition: 1 = Birth: Patient born with diabetes on start date; 2 = Diabetes Diagnosis: Patient diagnosed with diabetes on start date; 3 = Transferred In: Patient transferred in with diabetes diagnosis

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	Not Recorded	0%	Not Recorded	No	No	No	
Belgium	Not Recorded	0%	Not Recorded	No	No	No	
Croatia	Not Recorded	0%	Not Recorded	No	No	No	
Cyprus	Not Recorded	0%	Not Recorded	No	No	No	will start recording now
Germany	Not Recorded	0%	Not Recorded	No	No	No	
Hungary	Not Recorded	0%	Not Recorded	No	No	No	
Ireland	Not Recorded	0%	Not Recorded	No	No	No	
Italy	Not Recorded	0%	Not Recorded	No	No	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	Not Recorded	0%	Not Recorded	No	No	No	
Norway	Not Recorded	0%	Not Recorded	No	No	No	

Romania	High	40%	High	No	Yes	Yes	
Scotland	High	90%	High	No	Yes	Yes	I don't know what this means?
Slovenia	Not Recorded	0%	Not Recorded	No	No	No	
Sweden	Not Recorded	0%	Not Recorded	No	No	No	Not sure I understand this one correctly

Commentary: See ‘Activity Start Date.’

Validity: Low

6.50 Activity End Date

Definition: Date of completion of current period of patient activity

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	Not Recorded	95%	Not Recorded	No	No	No	Due to the fact, that fqsd data is mainly collected in an outpatient area 75% of the datasets have the same value for AD_START_DATE and AD_END_DATE
Belgium	Not Recorded	0%	Not Recorded	No	No	No	
Croatia	Not Recorded	0%	Not Recorded	No	No	No	
Cyprus	Not Recorded	0%	Not Recorded	No	No	No	will start recording now
Germany	Not Recorded	95%	Not Recorded	No	No	No	Due to the fact, that fqsd data is mainly collected in an outpatient area 75% of the datasets have the same value for AD_START_DATE and AD_END_DATE
Hungary	Not Recorded	0%	Not Recorded	No	No	No	
Ireland	Low	0%	Low	No	Yes	Yes	Dates of clinic visits recorded. Possible to calculate activity intervals.
Italy	Not Recorded	0%	Not Recorded	No	No	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	Not Recorded	0%	Not Recorded	No	No	No	

Norway	Not Recorded	0%	Not Recorded	No	No	No	
Romania	High	20%	High	No	Yes	Yes	
Scotland	High	90%	High	No	Yes	Yes	I don't know what this means?
Slovenia	Not Recorded	0%	Not Recorded	No	No	No	
Sweden	Not Recorded	0%	Not Recorded	No	No	No	

Commentary: See ‘Activity Start Date.’

Validity: Low

6.51 Activity End Reason

Definition: 1 = Death: Patient with diabetes died on end date; 2 = Transferred Out: Patient with diabetes transferred out on end date; 3 = Lost to Follow-up: Patient with diabetes lost to follow up

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	Not Recorded	0%	Not Recorded	No	No	No	
Belgium	Not Recorded	0%	Not Recorded	No	No	No	
Croatia	Not Recorded	0%	Not Recorded	No	No	No	We record only death (from the official national mortality database)
Cyprus	Not Recorded	0%	Not Recorded	No	No	No	will start document now - have got the records since we started but did not know how to record them
Germany	Not Recorded	0%	Not Recorded	No	No	No	
Hungary	Not Recorded	0%	Not Recorded	No	No	No	
Ireland	Low	95%	Low	No	Yes	Yes	Data recorded using multiple fields. Unmappable.
Italy	Not Recorded	0%	Not Recorded	No	No	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	Not Recorded	0%	Not Recorded	No	No	No	

Norway	Not Recorded	0%	Not Recorded	No	No	No
Romania	High	40%	High	No	Yes	Yes
Scotland	High	90%	High	No	Yes	Yes
Slovenia	Not Recorded	0%	Not Recorded	No	No	No
Sweden	Not Recorded	0%	Not Recorded	No	No	No

Commentary: See ‘Activity Start Date.’

Validity: Low

6.52 Lipid-lowering Therapy

Definition: 1 = Yes Date of record of treatment using lipid lowering drugs is valid 0 = No Date of record of treatment using lipid lowering drugs is NULL or contains invalid date

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	Medium	65%	High	Yes	Yes	No	FQSD Data-item is true if a drug-treatment for Dyslipidemia is performed
Belgium	Medium	98%	Medium	No	Yes	Yes	I only know whether a patient was treated with hypolipemic treatment during the data collection year, yes or no. It is not stored as "the date of treatment".
Croatia	Low	29%	Medium	No	Yes	Yes	There is a field for Lipid-Lowering Therapy with Yes and No options.
Cyprus	High	100%	High	Yes	Yes	Yes	If patient is taking treatment using lipid lowering drugs this is recorded . However the date he/she has started the treatment is not recorded (very difficult to find as patient may be attending many doctors).
Germany	Medium	65%	High	Yes	Yes	No	FQSD Data-item is true if a drug-treatment for Dyslipidemia is performed
Hungary	Medium	90%	Medium	No	Yes	Yes	
Ireland	Medium	95%	Low	No	Yes	Yes	Medication is recorded individually, not categorised. Unmappable.
Italy	Not Recorded	0%	Not Recorded	No	No	No	
Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	

Malta	High	90%	High	No	Yes	Yes	At present this is recorded in our database but is not being captured properly by the BIRO database. We need to correct this at our end.
Norway	Medium	70%	High	No	Yes	Yes	
Romania	High	40%	High	No	Yes	Yes	
Scotland	High	90%	High	No	Yes	Yes	Can be derived from prescribing data
Slovenia	Medium	100%	High	No	Yes	Yes	
Sweden	High	90%	High	No	Yes	Yes	

Commentary: A high level of consistency is reported across partners, although completeness varies considerably. Where only the year of data collection is known, this can be recorded as a mid-year estimate.

Validity: High

6.53 Anti-Platelet Therapy

Definition: 1 = Yes Date of record of treatment using anti-platelet drugs is valid 0 = No Date of record of treatment using anti-platelet drugs is NULL or contains invalid date

Country	Quality Score	Completeness	Consistency	Mandatory	Recorded	Routine	Comments
Austria	Medium	65%	High	Yes	Yes	No	FQSD-Dataitem used to get BIRO-item antiplatelet_therapy is drug-treatment of coronary heart disease. If a coronary heart disease in FQSD is treated (with drugs) the BIRO-field ANTIPLATELET_THERAPY is 1
Belgium	Medium	98%	Medium	No	Yes	Yes	I only know whether a patient was treated with antiplatelets during the data collection year, yes or no. It is not stored as "the date of treatment".
Croatia	Not Recorded	0%	Not Recorded	No	No	No	
Cyprus	High	100%	High	Yes	Yes	Yes	same as item 48
Germany	Medium	65%	High	Yes	Yes	No	FQSD-Dataitem used to get BIRO-item antiplatelet_therapy is drug-treatment of coronary heart disease. If a coronary heart disease in FQSD is treated (with drugs) the BIRO-field ANTIPLATELET_THERAPY is 1
Hungary	Medium	95%	Medium	No	Yes	Yes	
Ireland	Medium	95%	Low	No	Yes	Yes	Medication is recorded individually, not categorised. Unmappable.
Italy	Not Recorded	0%	Not Recorded	No	No	No	

Luxembourg	Not Recorded	0%	Not Recorded	No	No	No	
Malta	High	90%	High	No	Yes	Yes	At present this is recorded in our databse but is not being captured properly by the BIRO database. We need to correct this at our end.
Norway	Medium	70%	High	No	Yes	Yes	
Romania	Not Recorded	0%	Not Recorded	No	No	No	
Scotland	High	90%	High	No	Yes	Yes	Can be derived from prescribing data
Slovenia	Not Recorded	0%	Not Recorded	No	No	No	No patients is receiving such therapy
Sweden	Not Recorded	0%	Not Recorded	No	No	No	

Commentary: Only just over half of the partners reported recording this data item in an acceptable way, meaning that it can only be categorised with low validity.

Validity: Low

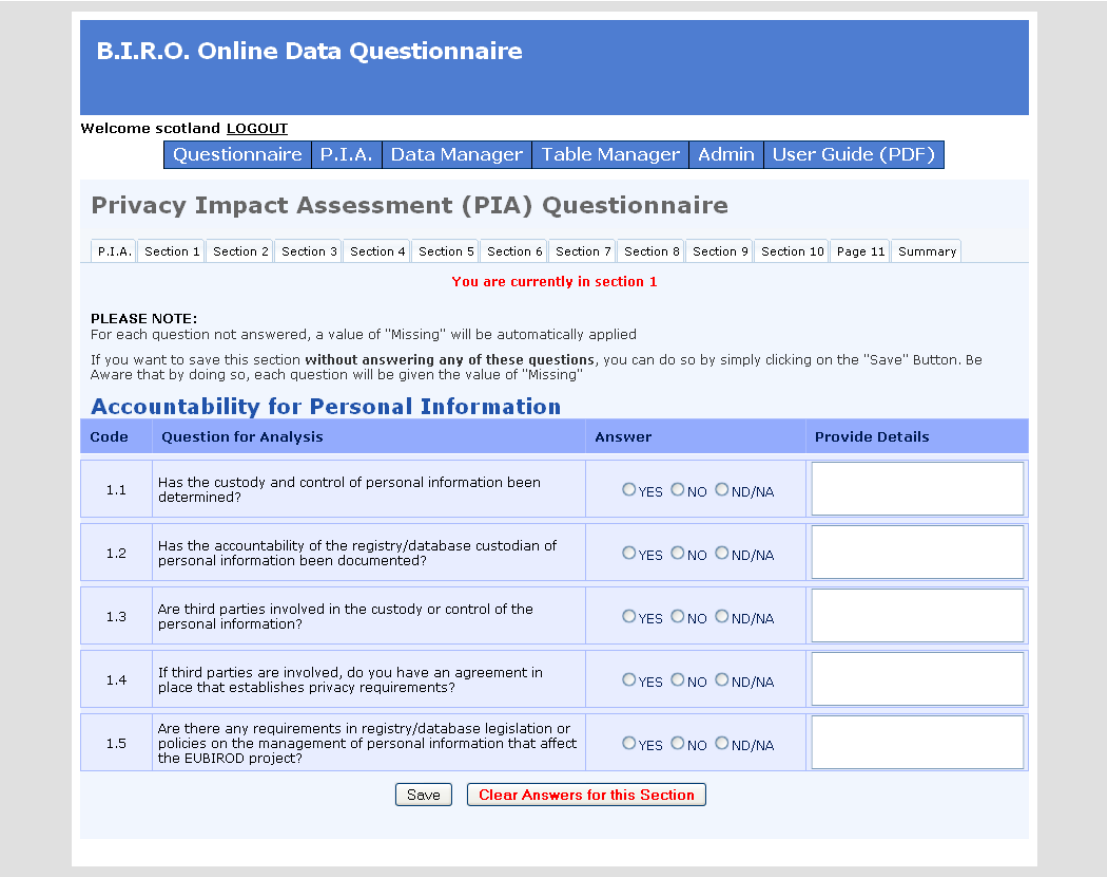
7. Dataset Analysis: Summary

The analysis exercise documented in the previous section shows the results of the clinical dataset metadata questionnaire for EUBIROD. This provides full detail and high level commentary of responses received to date for each data item and outlines where further improvements can be made. Section 8 will describe those data items that have modified or added as a result of this work.

7.1 Metadata Entry

Although some partners provided a considerable amount of local metadata in the form of their clinical comments, others reporting less than optimum data quality, completeness or consistency with the EUBIROD definitions failed to provide any meaningful explanation for this. Although this was disappointing, many partners reported that the 'wizard' format of the questionnaire was on occasion time-consuming to enter information due to the fact that user must click through every data item individually.

Recent developments within the EUBIROD project have included an alternative questionnaire format for the Privacy Impact Assessment. This is structured based on several sections broken down by category leading to a much quicker data entry and review solution (see below).



It is proposed that the metadata questionnaire is reviewed to enhance the user experience and so that the questionnaires are consistent and encourage

more comments from partners. Indeed, partners reporting data quality below a certain threshold can be prompted to include a comment. Logical sections can be factored in based on the types of clinical data recorded. Relevant sections were documented in the original BIRO data dictionary as follows:

- Profile Data (e.g. Patient ID, Type of Diabetes, Sex)
- Risk Factors (e.g. Smoking Status, Alcohol Status)
- Measurements (e.g. Weight, Blood Pressure)
- Lab Tests (e.g. HbA1c, Cholesterol)
- Assessments (e.g. Eye and Foot Screening data)
- Outcomes (e.g. Renal and Cardiovascular Outcomes)
- Treatments (e.g. Drug Therapies)
- Self Management (e.g. Self-Monitoring, Education)

It is believed that the metadata captured through this process can be unrivalled.

7.2 High Validity Data Items

Although EUBIROD aspires to report consistently on all of its 'Core Indicators', it is clear that some carry more weight and comparability than others. These are items where there is high consistency, quality and completeness. It is proposed that these 'gold-standard' data items are emphasised as being of the highest standard of excellence when reported, indicating the confidence held in the contributing data and subsequent outputs.

7.3 Default Dates

Although some partners record dates associated with clinical data accurately, many have reported issues with data indicating that only the year is known, or that diagnosis information is incomplete.

In these circumstances, clear rules are defined:

1. Where only year is known, a mid year estimate must be used to minimise the error rate. For example, if data is reported from 2009, the data mapped in the extract would be 01/07/2009. This therefore minimises the error rate to 6 months.
2. Where date of diabetes diagnosis or year of a prevalent outcome (e.g. MI, Stroke) is unknown the date 01/01/1900 may be used.

7.4 Laterality

Although some partners record details of both left and right status for feet or eyes, EUBIROD is only concerned, at this time, with the prevalent result. For example, if a patient has no retinopathy in their left eye, but has background retinopathy in their right eye, the prevailing status must be based on the 'worst' result. These data items may be reviewed at a later date, but for now the objective is to prevent individual patients from being counted more than once.

7.5 General Observations

Many partners require the analysis of data from multiple data sources that are configured and collect data in different way. This has led to the definition of

‘sub-data sources’ under the local umbrella where further comment can be added based on where the original data resides. For example, in Austria, data is sourced from insurance and clinical systems, meaning that it would be more appropriate to document each individually, rather than one general questionnaire response. This revised method of data capture is currently in development.

Data from Slovenia and Luxembourg are sourced from Paediatric data sources. This means that their clinical systems are not designed to record some of the long-term complications required by EUBIROD. Further, general metadata must be captured on each contributing data source to capture general comments not restricted to an individual item.

Although there has been some discussion surrounding clinical blindness vs blindness registration, the criteria required by Austria and Germany for blindness registration has been shown as consistent with the clinical definition given.

Unexpectedly, many long-term outcomes were not well recorded by all partners. In particular, renal complications are not available in several repositories, made even more surprising by the fact that one of the objectives of the St Vincent Declaration in 1989 was to “*Reduce numbers of people entering end-stage diabetic renal failure by at least one third*”.

7.6 Patient Activity Status

Finally, there was clearly ambiguity about the concept of periods of patient activity. This was discussed and clarification given at the EUBIROD meeting in Rome, June 2010. During these discussions it became clear that most partners cannot provide accurate information on patient activity at present, however this must be a concept to aspire to deliver good quality indicators. ‘Patient Activity Status’ is fully reiterated and expanded upon below for information.

The original BIRO Data Dictionary made the assumption that data would only be exported for patients currently active within a geographical area, or a specific clinic or data source. This was designed in order to simplify the data extraction process so that data could be compared based on a time-stamped extract.

It was agreed at the project meeting in January 2009 that it would be useful to be able to track a patients’ periods of ‘activity’ if the contributing data source is able to supply this information. It would also allow for more sophisticated statistical analyses.

The changes agreed were to allow a series of activity start and end dates, alongside a corresponding reason for status change. Agreed Activity Start Reason’s are:

- Birth
- Diabetes Diagnosis

- Transferred In

Agreed Activity End Reasons are:

- Death
- Transferred Out
- Lost to Follow-up

It is possible, therefore, for a patient to have one continuous or several disjointed periods of clinical activity based on their diagnosis dates, location of residence or follow up status. This means that ‘active’ patients who have not attended a clinical data source during a reporting period are not erroneously excluded from analysis. This is particularly useful to ensure that patients are not lost in the system and that they receive the care to which they are entitled to or require.

8. Dataset Revision

This section describes dataset modifications as a result of the review process. A short summary of the revised dataset can be viewed in Appendix 2.

8.1 Amended Clinical Dataset Items

The section shows the existing EUBIROD dataset items that have been modified as part of the review process.

8.1.1 Triglycerides

The original definition simply stated "*Value in mmol/L*". This has been amended to state "*Serum triglycerides can be either fasted or unfasted*".

8.1.2 Diabetes Specific Education

The original definition was vague and unusable stating "*This is very difficult to define and has not been defined until now. SDCD holds fields for advice on diet and pregnancy only. DiabCare holds many educational fields: general advice, healthy eating, hypoglycaemia, etc*".

The definition has now been clarified to state:
"*Non-specialist diabetes-related education which may be delivered in verbal, written or multimedia format. Topics of education may include: healthy eating and diet, illness, renal, hypoclycaemia, exercise, pregnancy*"

8.1.3 Diabetes Disease Management Programme

This data item was formerly named "*Patient Enrolment in Disease Management Programme (DMP) for Diabetes*", although this has been amended along with the clinical definition to emphasise that this it describing a structured education programme:

Parameter:	Diabetes Disease Management Programme	
BIRO Ref:	BIRO048	
Field Name:	ENROL_DMP	
Data Type:	Enumerated(0, 1)	
Definition:	Patient enrolment in a structured educational programme for diabetes, managed by a diabetes specialist health care professional	
	1 = Yes	Date of record of patient enrolment in structured Diabetes Disease Management Programme
	0 = No	Date of record of patient enrolment in structured Diabetes Disease Management Programme is NULL or contains invalid date

8.1.4 Hypertension

It was noted that Hypertension was poorly recorded, however there is clearly scope for mappings based on Systolic and Diastolic blood pressures and patients who are on hypertensive treatment. FQSD define hypertension as "Systolic blood pressure over 140 AND Diastolic blood pressure over 90". This may also be used for EUBIROD purposes.

8.2 New Clinical Dataset Items

8.2.1 Distinct Oral Drug Therapies

In order to better support the core BIRO Box and statistical analysis, it has been requested the all oral drug therapies are split into distinct data items. These have now been created as follows:

Parameter:	Sulphonylurea Therapy	
BIRO Ref:	BIRO055	
Field Name:	SUPHONYLUREAS	
Data Type:	Enumerated(0, 1)	
Definition:	Patient recorded as receiving Sulphonylurea treatment	
	0	Sulphonylurea therapy field contains valid year number
	1	Sulphonylurea therapy field is NULL or contains invalid numeric data
Mandatory:	No	
Validity:	Medium	
Data Mapping:	For NHS Scotland data, oral drug therapy will be extracted using prescribed drug British National Formulae (BNF) Code	

Parameter:	Biguanide Therapy	
BIRO Ref:	BIRO056	
Field Name:	BIGUANIDES	
Data Type:	Enumerated(0, 1)	
Definition:	Patient recorded as receiving Biguanide treatment	
	0	Biguanide therapy field contains valid year number
	1	Biguanide therapy field is NULL or contains invalid numeric data
Mandatory:	No	
Validity:	Medium	
Data Mapping:	For NHS Scotland data, oral drug therapy will be extracted using prescribed drug British National Formulae (BNF) Code	

Parameter:	Glucosidase Inhibitor Therapy	
BIRO Ref:	BIRO057	
Field Name:	GLUCOSIDASE_INHIBITOR	
Data Type:	Enumerated(0, 1)	
Definition:	Patient recorded as receiving Glucosidase Inhibitor treatment	
	0	Glucosidase Inhibitor therapy field contains valid year number
	1	Glucosidase Inhibitor therapy field is NULL or contains invalid numeric data
Mandatory:	No	
Validity:	Medium	
Data Mapping:	For NHS Scotland data, oral drug therapy will be extracted using prescribed drug British National Formulae (BNF) Code	

Parameter:	Glitazone Therapy	
BIRO Ref:	BIRO058	
Field Name:	GLITAZONES	
Data Type:	Enumerated(0, 1)	
Definition:	Patient recorded as receiving Glitazone treatment	
	0	Glitazone therapy field contains valid year number
	1	Glitazone therapy field is NULL or contains invalid numeric

		data
Mandatory:	No	
Validity:	Medium	
Data Mapping:	For NHS Scotland data, oral drug therapy will be extracted using prescribed drug British National Formulae (BNF) Code	

Parameter:	Glinide Therapy	
BIRO Ref:	BIRO059	
Field Name:	GLINIDES	
Data Type:	Enumerated(0, 1)	
Definition:	Patient recorded as receiving Glinide treatment	
	0	Glinide therapy field contains valid year number
	1	Glinide therapy field is NULL or contains invalid numeric data
Mandatory:	No	
Validity:	Medium	
Data Mapping:	For NHS Scotland data, oral drug therapy will be extracted using prescribed drug British National Formulae (BNF) Code	

8.3 Items Removed from Clinical Dataset

8.3.1 Oral Drug Therapy

BIRO040: ORAL_THERAPY has been retired as there are now distinct data items for treatment using Sulphonylureas, Biguanides, Glucosidase Inhibitors, Glitazones and Glinides.

8.4 Clinical Items Requiring Future Review

8.4.1 Type of Diabetes

At present, EUBIROD supports only Type 1 diabetes, Type 2 diabetes and other diabetes type. Other specific types of diabetes were excluded due to the very small numbers compared to Type 1 and Type 2. Additional defined diabetes types may be added later, including LADA, MODY, Pancreatic Pathology, Secondary Diabetes, Drug Induced, etc but consensus is required to further expand the applicable diagnosis types.

8.4.2 Drug Therapy

New drug therapies for the treatment of diabetes appear regularly, however for this revision of the dataset, the existing definitions will be maintained.

8.4.3 HbA1c

Laboratories changing the way in which HbA1c results are reported. The International Federation of Clinical Chemistry (IFCC) has put forward a new reference measurement method after discussion with diabetes groups worldwide. This will make comparing HbA1c results from different laboratories and from research trials throughout the world much easier. For the purposes of EUBIROD, results will remain recorded as a percentage until this is recording method (mmol/mol) is more widely available.

8.4.4 Eye/Foot Laterality

As detailed earlier in this documentation laterality will be reviewed at a later date, but for now the dominant status of the patient will be used.

8.4.5 Waist circumference

The proposed definition is "*Waist circumference measured half way between costal margin and iliac crest (cm)*". This will be reviewed with partners in line with their local datasets.

8.4.6 Estimated Glomerular Filtration Rate (eGFR)

The proposed definition is "A record of the patient's Estimated Glomerular Filtration Rate (GFR) (mls/min)". This will be reviewed with partners in line with their local datasets.

8.4.7 Depression

Further analysis is required to determine how depression outcomes are measured and monitored. Evidence-based scoring systems may be used for this parameter.

8.4.8 *Previous Foot Ulcer*

For many partners, it is not possible to record whether a patient has an active ulcer, but it is known if they have a history of ulcers. Consideration will be given to a review of this data item to reflect this situation.

8.4.9 *Paediatric Data Items*

During the meeting Rome, June 2010 it became clear that those partners whose primary data sources are paediatric systems were unable to support the analysis of long-term complications of diabetes. To allow a more meaningful analysis of the information from these systems, the following data items have been suggested to enhance their reporting capabilities:

1. Age Range
    a. 0 – 4
    b. 5 – 9
    c. 10 – 14
2. BMI Standard Deviation Score (SDS)
3. Height Standard Deviation Score (SDS)
4. Weight Standard Deviation Score (SDS)
5. Birth Weight
6. Birth Length
7. Coeliac Disease
8. Hashimoto Thyroiditis
9. Other Autoimmune Disease
    a. Vitiligo
    b. Psoriasis
    c. Juvenile Idiopathic Arthritis (JIA)
    d. Other Unspecified Autoimmune Disease

8.5 Data Value Boundaries

During the BIRO Box development a new requirement became apparent in the need for reasonable data value boundaries for numerical and date formatted data items. All enumerated values are restricted to pre-defined 'controlled vocabularies', however clinical results had been received that were unrealistic (e.g. HbA1c = 0%). In order to filter out 'invalid' results, precise upper and lower data boundaries have now been applied to all data items. The extended list, excluding enumerated types, now consists of the following:

Parameter	Lower Boundary	Upper Boundary
Date of Birth	≥01/01/1900	Current Date
Date of Diagnosis	≥DOB	Current Date
Episode Date	≥DOB	Current Date
Cigarettes per day	0	100
Alcohol Intake	0	60
Weight	5	300
Height	0.3	3
Body Mass Index	0.01	100
Systolic Blood Pressure	10	400
Diastolic Blood Pressure	10	300
HbA1c	2.15	25.02
Creatinine	3	1999
Total Cholesterol	0.01	50
HDL	0.01	5
Triglycerides	0.01	100
Average Injections	0	20
LDL	0.01	15
Commencement of patient activity	≥DOB	Current Date
Completion of patient activity	≥DOB	Current Date

8.6 Background Populations

During the development of the EUBIROD software, it became clear that a method of obtaining aggregate populations was necessary to support the EUBIROD indicators. This section describes the data items captured for both the general and diabetic populations covered by the geographical catchment area.

8.6.1 The BIRO Population table

This data relates to the total population and includes total male and female population and death figures by calendar year:

Reference	BIRO Name	Parameter	Data Type	Enumerated Values
BIRO002	DS_ID	Data Source ID	Enumerated	See Appendix 2
BIRO099	SUB_DS_ID	Sub Data Source ID	Enumerated	
BIRO300	YEAR	Year	Date/Year	
BIRO310	AGEBAND	Age band	Enumerated	1=0,14 2=15,24

				3=25,34 4=35,44 5=45,54 6=55,64 7=65,74 8=75,84 9=85+
BIRO301	POP_M	Total Male Population	Integer	
BIRO302	POP_F	Total Female Population	Integer	
BIRO303	DEATHS_M	Total Deaths in Male Population	Integer	
BIRO304	DEATHS_F	Total Deaths in Female Population	Integer	

8.6.2 The BIRO Diabetic population table

This data relates to the diabetic population and includes total males and females by calendar year

Reference	**BIRO Name**	**Parameter**	**Data Type**	**Enumerated Values**
BIRO002	DS_ID	Data Source ID	Enumerated	See Appendix 2
BIRO099	SUB_DS_ID	Sub Data Source ID	Enumerated	
BIRO300	YEAR	Year	Date/Year	
BIRO310	AGEBAND	Age band	Enumerated	1=0,14 2=15,24 3=25,34 4=35,44 5=45,54 6=55,64 7=65,74 8=75,84 9=85+
BIRO003	TYPE_DM	Type of Diabetes	Enumerated	1=Type 1 2=Type 2 3=Other
BIRO305	POP_D_M	Total Diabetic in Male Population	Integer	
BIRO306	POP_D_F	Total Diabetic in Female Population	Integer	

9. XML Update

As noted during the BIRO D4.2 evaluation, the original schema was overly flexible and requires a considerable amount of understanding by those involved in the data extraction process in order to implement it. A full schema review has been performed in order to 'lock-down' and constrain output to value expected in the definitions, particularly for those incorporating enumerated values. This section outlines the main changes, while Appendix 3 documents the full schema. Please note, that an XML schema has not been produced for describing background populations as the BIRO Box currently uses a predefined .csv format for this data.

9.1 Sub-data Sources

As explained earlier in this deliverable, many partners require the analysis of data from multiple data sources that are configured and collect data in different ways. 'Sub-data sources' can now be described, with data extracted under a local umbrella. This revised method of data capture is currently in development, however the schema has been modified to support this concept:

```
<xsd:element name="DataHeader">
  <xsd:complexType>
    <xsd:sequence>
      <xsd:element name="DateCreated" type="xsd:date"/>
      <xsd:element name="DS_ID" type="DataSource" id="BIRO002">
      <xsd:annotation>
        <xsd:documentation>Unique centre identification number (Defined as a BIRO Clinical
                                                                                    Site)</xsd:documentation>
      </xsd:annotation>
      </xsd:element>
      <xsd:element name="SUB_DS_ID" type="xsd:string" minOccurs="0"/>
    </xsd:sequence>
  </xsd:complexType>
</xsd:element>
```

The revised data header documents the main partner data source identifier, for example DARTS, Tayside. If a specific extract was required from a specific hospital clinic, a unique sub-data source identifier can be used that contributes to the DARTS, Tayside analysis.

9.2 Patient Profile

In order to support a database structure that is more easily to manipulate, patient profile data items that are required only once are separated from the main clinical data. This includes non-event-based data such as patient identifier, date of diagnosis and date of birth as is defined as follows:

```
<xsd:element name="Profile">
  <xsd:annotation>
    <xsd:documentation>The patient profile is non-event-based data such as surname, date of diagnosis and date of
                                                                                    birth</xsd:documentation>
  </xsd:annotation>
  <xsd:complexType>
    <xsd:sequence>
      <xsd:element name="PAT_ID" type="xsd:string" id="BIRO001"/>
      <xsd:element name="TYPE_DM" type="DiabetesType" id="BIRO003" minOccurs="0"/>
      <xsd:element name="SEX" type="GenderType" id="BIRO004" minOccurs="0"/>
      <xsd:element name="DOB" type="xsd:date" id="BIRO005" minOccurs="0"/>
      <xsd:element name="DT_DIAG" type="xsd:date" id="BIRO006" minOccurs="0"/>
```

```
    </xsd:sequence>
  </xsd:complexType>
</xsd:element>
```

9.3 Patient Episode Data

Again, to support a database structure that is more easily to manipulate, patient episode data items have been restructured to enhance the BIRO Box storage and subsequent analysis. This includes all process and long-term outcomes and assessments which can now be structured as follows:

```
<xsd:element name="EpisodeData" maxOccurs="unbounded">
  <xsd:annotation>
    <xsd:documentation>Patients have events that happen chrolonogocally (patient episodes)</xsd:documentation>
  </xsd:annotation>
  <xsd:complexType>
    <xsd:sequence>
      <xsd:element name="EPI_DATE" type="xsd:date" id="BIRO007"/>
      <xsd:element name="SMOK_STAT" type="SmokingStatusType" id="BIRO008" minOccurs="0"/>
      <xsd:element name="CIGS_DAY" type="xsd:integer" id="BIRO009" minOccurs="0"/>
      <xsd:element name="ALC_STAT" type="AlcoholStatusType" id="BIRO047" minOccurs="0"/>
      <xsd:element name="ALCOHOL" type="xsd:integer" id="BIRO010" minOccurs="0"/>
      <xsd:element name="WEIGHT" type="xsd:float" id="BIRO011" minOccurs="0"/>
      <xsd:element name="HEIGHT" type="xsd:float" id="BIRO012" minOccurs="0"/>
      .
      .
      .
      .
      <xsd:element name="LIPID_THERAPY" type="YesNoType" id="BIRO053" minOccurs="0"/>
      <xsd:element name="ANTIPLATELET_THERAPY" type="YesNoType" id="BIRO054" minOccurs="0"/>
    </xsd:sequence>
  </xsd:complexType>
</xsd:element>
```

Each data item can be formally included directly alongside the associated episode date.

A further split of episode data is recommended to enhance database optimisation in the BIRO Box and improved performance in the statistical analysis. For example:

- Risk Factors (e.g. Smoking Status, Alcohol Status)
- Measurements (e.g. Weight, Blood Pressure)
- Lab Tests (e.g. HbA1c, Cholesterol)
- Assessments (e.g. Eye and Foot Screening data)
- Outcomes (e.g. Renal and Cardiovascular Outcomes)
- Treatments (e.g. Drug Therapies)
- Self Management (e.g. Self-Monitoring, Education)

These groupings would clearly make the logical data separation more obvious to the reader. Although the original schema was designed to enable consistent data capture, and not necessarily to influence BIRO Software development, a more structured approach to data design would have the benefits of benefiting both approaches.

9.4 Formalised Enumerated Data Types

A key recommendation of the BIRO Evaluation was to provide more formalised schema structure to ensure that enumerated types were restricted

to their defined values, as well as restricting non-enumerated types to their defined numeric types (integer, float).

The following enumerated types are:

- DiabetesType
- GenderType
- SmokingStatusType
- AlcoholStatusType
- MicroalbuminuriaTestType
- YesNoType
- RetinopathyType
- MaculopathyType
- NormalAbnormalType
- DrugTherapyType
- SelfMonitoringType

Examples of ‘DiabetesType’ and the more generic ‘YesNoType’ used for multiple items are shown as examples below:

```
<xsd:simpleType name="DiabetesType">
  <xsd:restriction base="xsd:positiveInteger">
    <xsd:enumeration value="1">
      <xsd:annotation>
        <xsd:documentation>Type 1</xsd:documentation>
      </xsd:annotation>
    </xsd:enumeration>
    <xsd:enumeration value="2">
      <xsd:annotation>
        <xsd:documentation>Type 2</xsd:documentation>
      </xsd:annotation>
    </xsd:enumeration>
    <xsd:enumeration value="3">
      <xsd:annotation>
        <xsd:documentation>Other Types of Diabetes</xsd:documentation>
      </xsd:annotation>
    </xsd:enumeration>
  </xsd:restriction>
</xsd:simpleType>
```

```
<xsd:simpleType name="YesNoType">
    <xsd:restriction base="xsd:integer">
      <xsd:enumeration value="0">
        <xsd:annotation>
          <xsd:documentation>no</xsd:documentation>
        </xsd:annotation>
      </xsd:enumeration>
      <xsd:enumeration value="1">
        <xsd:annotation>
          <xsd:documentation>yes</xsd:documentation>
        </xsd:annotation>
      </xsd:enumeration>
    </xsd:restriction>
  </xsd:simpleType>
```

The ‘YesNoType’ is used for the new drug therapy types defined earlier in this document.

9.5 Formalised Non-Enumerated Data Types

In order to formalise the non-enumerated EUBIROD data, restrictions have now been specified in the schema in line with the data item boundarie specified in section 8.5.

A simple data type has been created for each numerical value, detailing maximum and minimum values, as in the example below:

```
<xsd:simpleType name="Injections">
  <xsd:restriction base="xsd:integer">
    <xsd:minInclusive value="0"/>
    <xsd:maxInclusive value="20"/>
  </xsd:restriction>
</xsd:simpleType>
```

A similar structure has been created for date values as in the example below:

```
<xsd:simpleType name="DateOfBirth">
  <xsd:restriction base="xsd:date">
    <xsd:minInclusive value="1900-01-01"/>
    <xsd:maxInclusive value="2010-12-12"/>
  </xsd:restriction>
</xsd:simpleType>
```

Appendix 1: Data Analysis Questionnaire User Guide

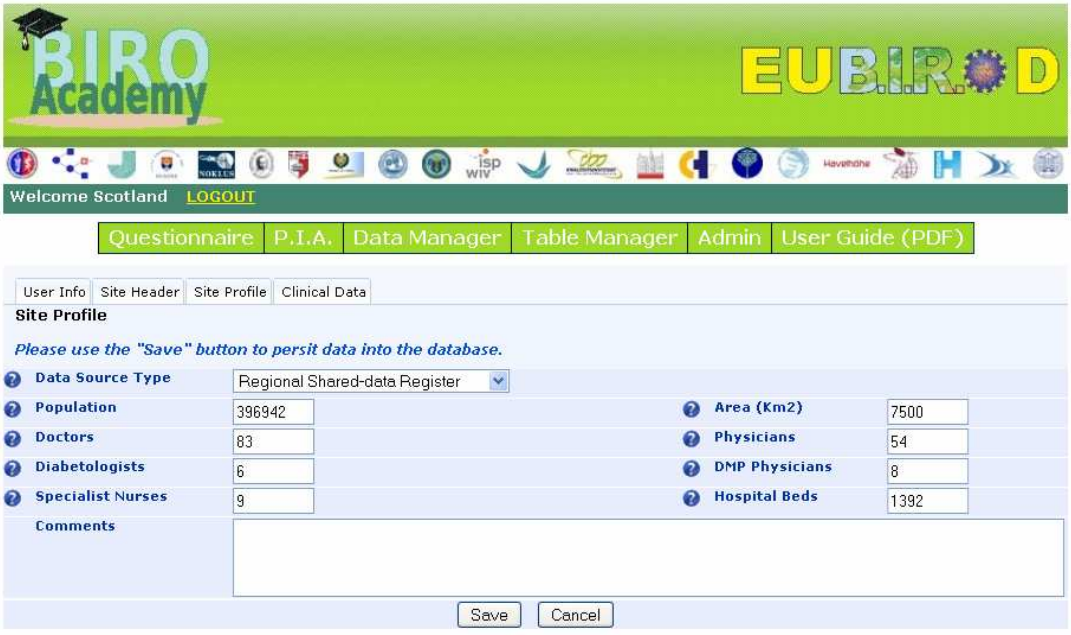
This document describes the EUBIROD Data Source Questionnaire, designed to capture important 'metadata' required to accurately describe local differences in data collection, data standards and data quality across all partners. This information will allow deviations from standardised definitions to be documented in order to help explain differences in aggregate data comparisons, and in order to better understand the data available within each country or region supplying data.

The questionnaire can be found at:
http://questionnaire.eubirod.eu/

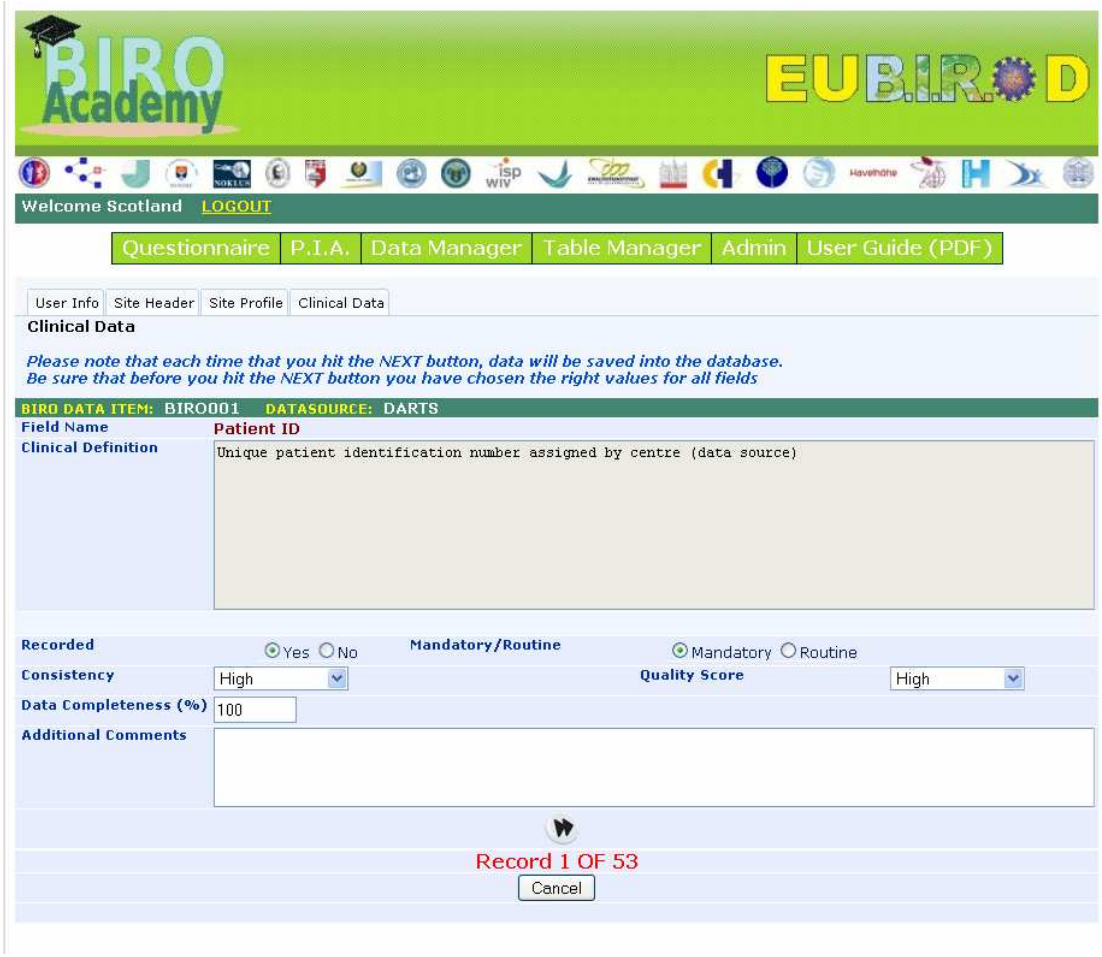
Begin by entering the username and password supplied to you, then start the questionnaire.

Enter your name and then click 'Next'.

The first data entry screen captures information about the partner supplying the information. Further information about the data item required can be found by hovering over the '?' icon.



The second data entry screen covers key figures describing the geographical area covered by the data source.



From this point onwards, the data capture focuses on the core BIRO Clinical Data. The data item is displayed on screen alongside the standardised definition.

The following data must be entered in order to proceed to the next data item:

- Recorded: Indicates whether or not the data item is recorded. Subsequent fields allow the user to enter whether recording is mandatory, or whether it occurs routinely within regular care.
- Consistency with the definition
    - High: Exact match
    - Medium: Minor discrepancy – e.g. Source units require mapping
    - Low: Major discrepancy – e.g. mapping unavailable
- Overall Quality Score: a value judgement on the ability for the data source to provide complete and consistent data in line with the definition
    - High: Can provide complete and consistent data
    - Medium: Minor completeness and consistency issues
    - Low: Major completeness and consistency issues
- Data Completeness: An indication of what percentage of the diabetic population have this data item recorded
- Additional Comments: This field should be used to describe any further information known about the data item at source that may affect longitudinal analysis or data presentation. Examples below:
    - "Some clinical/administration systems allow retrospective and prospective dates to be entered thus some error occur"
    - "In Aug 2002, HbA1c was DCCT aligned. 2009, was IFCC aligned. There is mapping in place for these."

Advance to the next data item by clicking '  '.

The full data item list is as follows:

1. Patient Identifier
2. Type of Diabetes
3. Sex
4. Date of Birth
5. Year of Diagnosis
6. Episode Date
7. Smoking Status
8. Cigarettes Per Day
9. Alcohol Status
10. Alcohol Intake
11. Weight
12. Height
13. Body Mass Index
14. Systolic Blood Pressure
15. Diastolic Blood Pressure
16. HbA1c
17. Creatinine
18. Microalbumin Testing
19. Total Cholesterol
20. HDL Cholesterol
21. LDL Cholesterol
22. Triglycerides
23. Retinal Examination
24. Retinopathy Status
25. Maculopathy
26. Foot Examination
27. Foot Pulses
28. Foot Sensation
29. End Stage Renal Failure
30. Renal Dialysis
31. Renal Transplant
32. Stroke
33. Active Foot Ulcer
34. Myocardial Infarction
35. Laser
36. Hypertension
37. Blindness
38. Amputation
39. Antihypertensive Medication
40. Hypoglycaemic Drug Therapy
41. Oral Drug Therapy
42. Pump Therapy
43. Inhaled Therapy
44. Average Injections
45. Self Monitoring
46. Diabetes Specific Education
47. Patient Enrolment in Disease Management Programme
48. Lipid-Lowering Therapy
49. Anti-platelet Therapy
50. Activity Start Date
51. Activity Start Reason
52. Activity End Date
53. Activity End Reason

Appendix 2: Short Dataset – Clinical Parameters

Reference	Field Name	Parameter	Data Type	Enumerated / Boundary Values
BIRO001	PAT_ID	Patient ID	String(12)	
BIRO002	DS_ID	Data Source ID	Enumerated	1 = DARTS Dataset, Tayside, Scotland 2 = Umbria Dataset, Italy 3 = FQSD, Austria 4 = Telemed, Romania 5 = Noklus, Norway 6 = Diabetes Register, Cyprus 7 = CDM Program, Malta 8 = NEPI foundation, Sweden 9 = University of Debrecen, Hungary 10 = Scientific Institute of Public Health, Belgium 11 = Adelaide and Meath Hospital , Ireland 12 = Dutch Institute for Healthcare Improvement, Netherlands 13 = University of Ljubljana, Slovenia 14 = Centre Hospitalier de Luxembourg, Luxembourg 15 = IMABIS Foundation, Spain 16 = Medical University of Silesia, Poland 17 = Havelhohe Hospital, Germany 18 = Hillerod University Hospital, Denmark 19 = Vuk Vrhovac University Clinic, Croatia 20 = DASMAN Centre , Kuwait 21 = IDF, Belgium 22 = Serectrix, Italy

BIRO003	TYPE_DM	Type Of Diabetes	Enumerated	1 = Type 1 2 = Type 2 3 = Other Types of Diabetes
BIRO004	SEX	Sex	Enumerated	1 = Male 2 = Female
BIRO005	DOB	Date of Birth	Date/Time	Range: ≥01/01/1900 - <Current Date
BIRO006	DT_DIAG	Date of Diagnosis	Date/Time	Range: ≥DOB - <Current Date
BIRO007	EPI_DATE	Episode Date	Date/Time	Range: ≥DOB - <Current Date
BIRO008	SMOK_STAT	Smoking Status	Enumerated	1 = Current Smoker 2 = Non-Smoker 3 = Ex-Smoker
BIRO009	CIGS_DAY	Cigarettes per day	Integer	Range: 0 – 100
BIRO010	ALCOHOL	Alcohol Intake	Integer	Range: 0 – 60
BIRO011	WEIGHT	Weight	Real	Range: 5 – 300
BIRO012	HEIGHT	Height	Real	Range: 0.3 – 3
BIRO013	BMI	Body Mass Index	Real	Range: 0.01 – 100
BIRO014	SBP	Systolic Blood Pressure	Integer	Range: 10 – 400
BIRO015	DBP	Diastolic Blood Pressure	Integer	Range: 10 – 300
BIRO016	HBA1C	HbA1c	Real	Range: 2.15 – 25.02
BIRO017	CREAT	Creatinine	Integer	Range: 3 – 1999
BIRO018	MA_TEST	Microalbumin	Enumerated	1 = MA Test Normal 2 = MA Test Abnormal 0 = No MA Test Recorded
BIRO019	CHOL	Total Cholesterol	Real	Range: 0.01 – 50
BIRO020	HDL	HDL	Real	Range: 0.01 – 5
BIRO021	TG	Triglycerides	Real	Range: 0.01 – 100
BIRO022	RETINAL_EXAM	Retinal Examination	Enumerated	1 = Yes 0 = No
BIRO023	RETINA	Retinopathy Status	Enumerated	1 = No Retinopathy 2 = Background Retinopathy 3 = Referable Retinopathy
BIRO024	MACULA	Maculopathy Status	Enumerated	1 = No Maculopathy 2 = Referable Maculopathy
BIRO025	FOOT_EXAM	Foot Examination	Enumerated	1 = Yes 0 = No
BIRO026	PULSES	Foot Pulses	Enumerated	1 = Present

				0 = Absent
BIRO027	FTSENS	Foot Sensation	Enumerated	1 = Normal 0 = Abnormal
BIRO028	ESRF	End Stage Renal Therapy	Enumerated	1 = Yes 0 = No
BIRO029	DIALYSIS	Renal Dialysis	Enumerated	1 = Yes 0 = No
BIRO030	TRANSPLANT	Renal Transplant	Enumerated	1 = Yes 0 = No
BIRO031	STROKE	Stroke	Enumerated	1 = Yes 0 = No
BIRO032	ULCER	Active Foot Ulcer	Enumerated	1 = Yes 0 = No
BIRO033	MI	Myocardial Infarction	Enumerated	1 = Yes 0 = No
BIRO034	LASER	Laser	Enumerated	1 = Yes 0 = No
BIRO035	HYPERTENSION	Hypertension	Enumerated	1 = Yes 0 = No
BIRO036	BLIND	Blindness	Enumerated	1 = Yes 0 = No
BIRO037	AMPUT	Amputation	Enumerated	1 = Yes 0 = No
BIRO038	HYPERT_MED	Antihypertensive Medication	Enumerated	1 = Yes 0 = No
BIRO039	DRUG_THERAPY	Hypoglycaemic Drug Therapy	Enumerated	1 = Insulin Only 2 = Tablet Only 3 = Insulin and Tablets 4 = None (Diet Only)
BIRO040	ORAL_THERAPY	Oral Drug Therapy	Enumerated	1 = Sulphonylureas 2 = Biguanides 3 = Glucosidase Inhibitors 4 = Glitazones 5 = Glinides
BIRO041	PUMP_THERAPY	Pump Therapy	Enumerated	1 = Yes 0 = No

BIRO042	NASAL_THERAPY	Nasal Therapy	Enumerated	1 = Yes 0 = No
BIRO043	INJECTIONS	Average Injections	Real	Range: 0 – 20
BIRO044	SELF_MON	Self Monitoring	Enumerated	1 = Urine 2 = Blood Glucose 3 = Both
BIRO045	EDUCATION	Diabetes Specific Education	Enumerated	1 = Yes 0 = No
BIRO046	LDL	LDL	Real	Range: 0.01 – 15
BIRO047	ALC_STAT	Alcohol Status	Enumerated	1 = Current Drinker 2 = Non-Drinker 3 = Ex-Drinker
BIRO048	DMP_ENROL	Patient Enrolment in DMP for Diabetes	Enumerated	1 = Yes 0 = No
BIRO049	AD_START_DATE	Data of commencement of period of patient activity	Date/Time	Range: ≥DOB - <Current Date
BIRO050	AD_START_REASON	Reason for the commencement of activity period	Enumerated	1 = Birth 2 = Diabetes Diagnosis 3 = Transferred In
BIRO051	AD_END_DATE	Data of completion of period of activity	Date/Time	Range: ≥DOB - <Current Date
BIRO052	AD_END_REASON	Reason for the completion of activity period	Enumerated	1 = Death 2 = Transferred Out 3 = Lost to Follow-up
BIRO053	LIPID_THERAPY	Lipid Lowering Therapy	Enumerated	1 = Yes 0 = No
BIRO054	ANTIPLATELET_THERAPY	Anti-platelet Therapy	Enumerated	1 = Yes 0 = No
BIRO055	SULPHONYLUREAS	Sulphonylurea Therapy	Enumerated	1 = Yes 0 = No
BIRO056	BIGUANIDES	Biguanide Therapy	Enumerated	1 = Yes 0 = No
BIRO057	GLUCOSIDASE_INHIBITORS	Glucoseidase Inhibitor Therapy	Enumerated	1 = Yes 0 = No
BIRO058	GLITAZONES	Glitazone Therapy	Enumerated	1 = Yes 0 = No

BIRO059	GLINIDES	Glinide Therapy	Enumerated	1 = Yes 0 = No
BIRO099	SUB_DS_ID	Sub data source identifier (Related to DS_ID)	Enumerated	TBC

Appendix 3: Revised Data Export Schema

The revised EUBIROD XML schema is shown in full below:

```
<?xml version="1.0" encoding="UTF-8"?>
<xsd:schema xmlns:xsd="http://www.w3.org/2001/XMLSchema" version="0.4">
  <xsd:include schemaLocation="BIRODataSet.xsd"/>
  <xsd:element name="ECDataExport">
    <xsd:annotation>
      <xsd:documentation>Created by Douglas Boyle, 2006-02-16</xsd:documentation>
      <xsd:documentation>Each participating client database / system / clinic / data source has a definition</xsd:documentation>
      <xsd:documentation>Amended by Scott Cunningham, 2007-03-23, version 0.2</xsd:documentation>
      <xsd:documentation>Split data source data from clinical data</xsd:documentation>
      <xsd:documentation>Added extra data fields existing in BIRO WP3 dataset</xsd:documentation>
      <xsd:documentation>Amended by Scott Cunningham, 2007-05-24, version 0.3</xsd:documentation>
      <xsd:documentation>Removal of duplicate element names</xsd:documentation>
      <xsd:documentation>Amended by Scott Cunningham, 2007-07-24, version 0.4</xsd:documentation>
      <xsd:documentation>Updated during Data Dictionary developments</xsd:documentation>
      <xsd:documentation>Amended by Scott Cunningham, 2009-03-17, version 0.5</xsd:documentation>
      <xsd:documentation>Added Activity Status and NUTS Classifications</xsd:documentation>
      <xsd:documentation>Amended by Valentina Baglioni/Scott Cunningham, 2010-05-17, version 0.6</xsd:documentation>
      <xsd:documentation>Major review of structure to improve BIRO Box performance</xsd:documentation>
    </xsd:annotation>
    <xsd:complexType>
      <xsd:sequence>
        <xsd:element name="DataHeader">
          <xsd:complexType>
            <xsd:sequence>
              <xsd:element name="DateCreated" type="xsd:date"/>
              <xsd:element name="DS_ID" type="DataSource" id="BIRO002">
                <xsd:annotation>
                  <xsd:documentation>Unique centre identification number (Defined as a BIRO Clinical Site)</xsd:documentation>
                </xsd:annotation>
              </xsd:element>
```

```
        <xsd:element name="SUB_DS_ID" type="xsd:string" minOccurs="0"/>
      </xsd:sequence>
    </xsd:complexType>
  </xsd:element>
  <xsd:element name="Patient">
    <xsd:complexType>
      <xsd:sequence>
        <xsd:element name="Profile">
          <xsd:annotation>
            <xsd:documentation>The patient profile is non-event-based data such as surname, date of diagnosis and date of birth</xsd:documentation>
          </xsd:annotation>
          <xsd:complexType>
            <xsd:sequence>
              <xsd:element name="PAT_ID" type="xsd:string" id="BIRO001"/>
              <xsd:element name="TYPE_DM" type="DiabetesType" id="BIRO003" minOccurs="0"/>
              <xsd:element name="SEX" type="GenderType" id="BIRO004" minOccurs="0"/>
              <xsd:element name="DOB" type="DateOfBirth" id="BIRO005" minOccurs="0"/>
              <xsd:element name="DT_DIAG" type="DateOfDiagnosis" id="BIRO006" minOccurs="0"/>
            </xsd:sequence>
          </xsd:complexType>
        </xsd:element>
        <xsd:element name="ActivityData" minOccurs="0" maxOccurs="unbounded">
          <xsd:complexType>
            <xsd:sequence>
              <xsd:element name="StartDate" type="ActivityStartDate"/>
              <xsd:element name="StartReason" type="ActivityStartReason"/>
              <xsd:element name="EndDate" type="ActivityEndDate" minOccurs="0"/>
              <xsd:element name="EndReason" type="ActivityEndReason" minOccurs="0"/>
            </xsd:sequence>
          </xsd:complexType>
        </xsd:element>
        <xsd:element name="EpisodeData" maxOccurs="unbounded">
          <xsd:annotation>
            <xsd:documentation>Patients have events that happen chrolonogocally (patient episodes)</xsd:documentation>
          </xsd:annotation>
          <xsd:complexType>
            <xsd:sequence>
```

```
<xsd:element name="EPI_DATE" type="EpisodeDate" id="BIRO007"/>
<xsd:element name="SMOK_STAT" type="SmokingStatusType" id="BIRO008" minOccurs="0"/>
<xsd:element name="CIGS_DAY" type="Cigarettes" id="BIRO009" minOccurs="0"/>
<xsd:element name="ALC_STAT" type="AlcoholStatusType" id="BIRO047" minOccurs="0"/>
<xsd:element name="ALCOHOL" type="Alcohol" id="BIRO010" minOccurs="0"/>
<xsd:element name="WEIGHT" type="Weight" id="BIRO011" minOccurs="0"/>
<xsd:element name="HEIGHT" type="Height" id="BIRO012" minOccurs="0"/>
<xsd:element name="BMI" type="BodyMassIndex" id="BIRO013" minOccurs="0"/>
<xsd:element name="SBP" type="SBP" id="BIRO014" minOccurs="0"/>
<xsd:element name="DBP" type="DBP" id="BIRO015" minOccurs="0"/>
<xsd:element name="HBA1C" type="HbA1c" id="BIRO016" minOccurs="0"/>
<xsd:element name="CREAT" type="Creatinine" id="BIRO017" minOccurs="0"/>
<xsd:element name="MA_TEST" type="MicroalbuminuriaTestType" id="BIRO018" minOccurs="0"/>
<xsd:element name="CHOL" type="Cholesterol" id="BIRO019" minOccurs="0"/>
<xsd:element name="HDL" type="HDL" id="BIRO020" minOccurs="0"/>
<xsd:element name="LDL" type="LDL" id="BIRO046" minOccurs="0"/>
<xsd:element name="TG" type="Triglycerides" id="BIRO021" minOccurs="0"/>
<xsd:element name="RETINAL_EXAM" type="YesNoType" id="BIRO022" minOccurs="0"/>
<xsd:element name="RETINA" type="RetinopathyType" id="BIRO023" minOccurs="0"/>
<xsd:element name="MACULA" type="MaculopathyType" id="BIRO024" minOccurs="0"/>
<xsd:element name="FOOT_EXAM" type="YesNoType" id="BIRO025" minOccurs="0"/>
<xsd:element name="PULSES" type="PresentAbsentType" id="BIRO026" minOccurs="0"/>
<xsd:element name="FTSENS" type="NormalAbnormalType" id="BIRO027" minOccurs="0"/>
<xsd:element name="ESRF" type="YesNoType" id="BIRO028" minOccurs="0"/>
<xsd:element name="DIALYSIS" type="YesNoType" id="BIRO029" minOccurs="0"/>
<xsd:element name="TRANSPLANT" type="YesNoType" id="BIRO030" minOccurs="0"/>
<xsd:element name="STROKE" type="YesNoType" id="BIRO031" minOccurs="0"/>
<xsd:element name="ULCER" type="YesNoType" id="BIRO032" minOccurs="0"/>
<xsd:element name="MI" type="YesNoType" id="BIRO033" minOccurs="0"/>
<xsd:element name="LASER" type="YesNoType" id="BIRO034" minOccurs="0"/>
<xsd:element name="HYPERTENSION" type="YesNoType" id="BIRO035" minOccurs="0"/>
<xsd:element name="BLIND" type="YesNoType" id="BIRO036" minOccurs="0"/>
<xsd:element name="AMPUT" type="YesNoType" id="BIRO037" minOccurs="0"/>
<xsd:element name="HYPERT_MED" type="YesNoType" id="BIRO038" minOccurs="0"/>
<xsd:element name="DRUG_THERAPY" type="DrugTherapyType" id="BIRO039" minOccurs="0"/>
<xsd:element name="PUMP_THERAPY" type="YesNoType" id="BIRO041" minOccurs="0"/>
<xsd:element name="NASAL_THERAPY" type="YesNoType" id="BIRO042" minOccurs="0"/>
```

```
                    <xsd:element name="INJECTIONS" type="Injections" id="BIRO043" minOccurs="0"/>
                    <xsd:element name="SELF_MON" type="SelfMonitoringType" id="BIRO044" minOccurs="0"/>
                    <xsd:element name="EDUCATION" type="YesNoType" id="BIRO045" minOccurs="0"/>
                    <xsd:element name="DMP_ENROL" type="YesNoType" id="BIRO048" minOccurs="0"/>
                    <xsd:element name="LIPID_THERAPY" type="YesNoType" id="BIRO053" minOccurs="0"/>
                    <xsd:element name="ANTIPLATELET_THERAPY" type="YesNoType" id="BIRO054" minOccurs="0"/>
                    <xsd:element name="SULPHONYLUREAS" type="YesNoType" id="BIRO055" minOccurs="0"/>
                    <xsd:element name="BIGUANIDES" type="YesNoType" id="BIRO056" minOccurs="0"/>
                    <xsd:element name="GLUCOSIDASE_INHIBITORS" type="YesNoType" id="BIRO057" minOccurs="0"/>
                    <xsd:element name="GLITAZONES" type="YesNoType" id="BIRO058" minOccurs="0"/>
                    <xsd:element name="GLINIDES" type="YesNoType" id="BIRO059" minOccurs="0"/>
                </xsd:sequence>
                  </xsd:complexType>
                </xsd:element>
              </xsd:sequence>
            </xsd:complexType>
          </xsd:element>
        </xsd:sequence>
      </xsd:complexType>
    </xsd:element>
    <!--simple types-->
    <xsd:simpleType name="DataSource">
      <xsd:restriction base="xsd:positiveInteger">
        <xsd:enumeration value="1">
          <xsd:annotation>
            <xsd:documentation>DARTS Dataset, Tayside, Scotland</xsd:documentation>
          </xsd:annotation>
        </xsd:enumeration>
        <xsd:enumeration value="2">
          <xsd:annotation>
            <xsd:documentation>Umbria Dataset, Italy</xsd:documentation>
          </xsd:annotation>
        </xsd:enumeration>
        <xsd:enumeration value="3">
          <xsd:annotation>
            <xsd:documentation>FQSD, Austria</xsd:documentation>
          </xsd:annotation>
```

```
</xsd:enumeration>
<xsd:enumeration value="4">
  <xsd:annotation>
    <xsd:documentation>Telemed, Romania</xsd:documentation>
  </xsd:annotation>
</xsd:enumeration>
<xsd:enumeration value="5">
  <xsd:annotation>
    <xsd:documentation>Noklus, Norway</xsd:documentation>
  </xsd:annotation>
</xsd:enumeration>
<xsd:enumeration value="6">
  <xsd:annotation>
    <xsd:documentation>Diabetes Register, Cyprus</xsd:documentation>
  </xsd:annotation>
</xsd:enumeration>
<xsd:enumeration value="7">
  <xsd:annotation>
    <xsd:documentation>CDM Program, Malta</xsd:documentation>
  </xsd:annotation>
</xsd:enumeration>
<xsd:enumeration value="8">
  <xsd:annotation>
    <xsd:documentation>NEPI foundation, Sweden</xsd:documentation>
  </xsd:annotation>
</xsd:enumeration>
<xsd:enumeration value="9">
  <xsd:annotation>
    <xsd:documentation>University of Debrecen, Hungary</xsd:documentation>
  </xsd:annotation>
</xsd:enumeration>
<xsd:enumeration value="10">
  <xsd:annotation>
    <xsd:documentation>Scientific Institute of Public Health, Belgium</xsd:documentation>
  </xsd:annotation>
</xsd:enumeration>
<xsd:enumeration value="11">
```

```
    <xsd:annotation>
      <xsd:documentation>Adelaide and Meath Hospital ,  Ireland</xsd:documentation>
    </xsd:annotation>
  </xsd:enumeration>
  <xsd:enumeration value="12">
    <xsd:annotation>
      <xsd:documentation>Dutch Institute for Healthcare Improvement, Netherlands</xsd:documentation>
    </xsd:annotation>
  </xsd:enumeration>
  <xsd:enumeration value="13">
    <xsd:annotation>
      <xsd:documentation>University of Ljubljana, Slovenia</xsd:documentation>
    </xsd:annotation>
  </xsd:enumeration>
  <xsd:enumeration value="14">
    <xsd:annotation>
      <xsd:documentation>Centre Hospitalier de Luxembourg, Luxembourg</xsd:documentation>
    </xsd:annotation>
  </xsd:enumeration>
  <xsd:enumeration value="15">
    <xsd:annotation>
      <xsd:documentation>IMABIS Foundation, Spain</xsd:documentation>
    </xsd:annotation>
  </xsd:enumeration>
  <xsd:enumeration value="16">
    <xsd:annotation>
      <xsd:documentation>Medical University of Silesia, Poland</xsd:documentation>
    </xsd:annotation>
  </xsd:enumeration>
  <xsd:enumeration value="17">
    <xsd:annotation>
      <xsd:documentation>Havelhohe Hospital, Germany</xsd:documentation>
    </xsd:annotation>
  </xsd:enumeration>
  <xsd:enumeration value="18">
    <xsd:annotation>
      <xsd:documentation>Hillerod University Hospital, Denmark</xsd:documentation>
```

```
      </xsd:annotation>
    </xsd:enumeration>
    <xsd:enumeration value="19">
      <xsd:annotation>
        <xsd:documentation>Vuk Vrhovac University Clinic, Croatia</xsd:documentation>
      </xsd:annotation>
    </xsd:enumeration>
    <xsd:enumeration value="20">
      <xsd:annotation>
        <xsd:documentation>DASMAN Centre , Kuwait</xsd:documentation>
      </xsd:annotation>
    </xsd:enumeration>
    <xsd:enumeration value="21">
      <xsd:annotation>
        <xsd:documentation>IDF , Belgium</xsd:documentation>
      </xsd:annotation>
    </xsd:enumeration>
    <xsd:enumeration value="22">
      <xsd:annotation>
        <xsd:documentation>Serectrix , Italy</xsd:documentation>
      </xsd:annotation>
    </xsd:enumeration>
  </xsd:restriction>
</xsd:simpleType>  <xsd:simpleType name="ActivityStartReason">
  <xsd:restriction base="xsd:positiveInteger">
    <xsd:enumeration value="1">
      <xsd:annotation>
        <xsd:documentation>Born</xsd:documentation>
      </xsd:annotation>
    </xsd:enumeration>
    <xsd:enumeration value="2">
      <xsd:annotation>
        <xsd:documentation>Diagnosed</xsd:documentation>
      </xsd:annotation>
    </xsd:enumeration>
    <xsd:enumeration value="3">
      <xsd:annotation>
```

```
            <xsd:documentation>Transferred In</xsd:documentation>
          </xsd:annotation>
        </xsd:enumeration>
      </xsd:restriction>
    </xsd:simpleType>
    <xsd:simpleType name="ActivityEndReason">
      <xsd:restriction base="xsd:positiveInteger">
        <xsd:enumeration value="1">
          <xsd:annotation>
            <xsd:documentation>Died</xsd:documentation>
          </xsd:annotation>
        </xsd:enumeration>
        <xsd:enumeration value="2">
          <xsd:annotation>
            <xsd:documentation>Transferred Out</xsd:documentation>
          </xsd:annotation>
        </xsd:enumeration>
        <xsd:enumeration value="3">
          <xsd:annotation>
            <xsd:documentation>Lost To Follow-up</xsd:documentation>
          </xsd:annotation>
        </xsd:enumeration>
      </xsd:restriction>
    </xsd:simpleType>
    <xsd:simpleType name="DiabetesType">
      <xsd:restriction base="xsd:positiveInteger">
        <xsd:enumeration value="1">
          <xsd:annotation>
            <xsd:documentation>Type 1</xsd:documentation>
          </xsd:annotation>
        </xsd:enumeration>
        <xsd:enumeration value="2">
          <xsd:annotation>
            <xsd:documentation>Type 2</xsd:documentation>
          </xsd:annotation>
        </xsd:enumeration>
        <xsd:enumeration value="3">
```

```
        <xsd:annotation>
          <xsd:documentation>Other Types of Diabetes</xsd:documentation>
        </xsd:annotation>
      </xsd:enumeration>
    </xsd:restriction>
  </xsd:simpleType>
  <xsd:simpleType name="GenderType">
    <xsd:restriction base="xsd:integer">
      <xsd:enumeration value="0">
        <xsd:annotation>
          <xsd:documentation>Not Recorded</xsd:documentation>
        </xsd:annotation>
      </xsd:enumeration>
      <xsd:enumeration value="1">
        <xsd:annotation>
          <xsd:documentation>Male</xsd:documentation>
        </xsd:annotation>
      </xsd:enumeration>
      <xsd:enumeration value="2">
        <xsd:annotation>
          <xsd:documentation>Female</xsd:documentation>
        </xsd:annotation>
      </xsd:enumeration>
    </xsd:restriction>
  </xsd:simpleType>
  <xsd:simpleType name="SmokingStatusType">
    <xsd:restriction base="xsd:positiveInteger">
      <xsd:enumeration value="1">
        <xsd:annotation>
          <xsd:documentation>Current Smoker</xsd:documentation>
        </xsd:annotation>
      </xsd:enumeration>
      <xsd:enumeration value="2">
        <xsd:annotation>
          <xsd:documentation>Non Smoker</xsd:documentation>
        </xsd:annotation>
      </xsd:enumeration>
```

```
      <xsd:enumeration value="3">
        <xsd:annotation>
          <xsd:documentation>Ex Smoker</xsd:documentation>
        </xsd:annotation>
      </xsd:enumeration>
    </xsd:restriction>
  </xsd:simpleType>
  <xsd:simpleType name="AlcoholStatusType">
    <xsd:restriction base="xsd:positiveInteger">
      <xsd:enumeration value="1">
        <xsd:annotation>
          <xsd:documentation>Current Drinker</xsd:documentation>
        </xsd:annotation>
      </xsd:enumeration>
      <xsd:enumeration value="2">
        <xsd:annotation>
          <xsd:documentation>Non Drinker</xsd:documentation>
        </xsd:annotation>
      </xsd:enumeration>
      <xsd:enumeration value="3">
        <xsd:annotation>
          <xsd:documentation>Ex Drinker</xsd:documentation>
        </xsd:annotation>
      </xsd:enumeration>
    </xsd:restriction>
  </xsd:simpleType>
  <xsd:simpleType name="MicroalbuminuriaTestType">
    <xsd:restriction base="xsd:integer">
      <xsd:enumeration value="0">
        <xsd:annotation>
          <xsd:documentation>No MA test recorder</xsd:documentation>
        </xsd:annotation>
      </xsd:enumeration>
      <xsd:enumeration value="1">
        <xsd:annotation>
          <xsd:documentation>MA test normal</xsd:documentation>
        </xsd:annotation>
```

```
      </xsd:enumeration>
      <xsd:enumeration value="2">
        <xsd:annotation>
          <xsd:documentation>MA test abnormal</xsd:documentation>
        </xsd:annotation>
      </xsd:enumeration>
    </xsd:restriction>
  </xsd:simpleType>
  <xsd:simpleType name="YesNoType">
    <xsd:restriction base="xsd:integer">
      <xsd:enumeration value="0">
        <xsd:annotation>
          <xsd:documentation>no</xsd:documentation>
        </xsd:annotation>
      </xsd:enumeration>
      <xsd:enumeration value="1">
        <xsd:annotation>
          <xsd:documentation>yes</xsd:documentation>
        </xsd:annotation>
      </xsd:enumeration>
    </xsd:restriction>
  </xsd:simpleType>
  <xsd:simpleType name="RetinopathyType">
    <xsd:restriction base="xsd:positiveInteger">
      <xsd:enumeration value="1">
        <xsd:annotation>
          <xsd:documentation>No Retinopathy</xsd:documentation>
        </xsd:annotation>
      </xsd:enumeration>
      <xsd:enumeration value="2">
        <xsd:annotation>
          <xsd:documentation>Background Retinopathy</xsd:documentation>
        </xsd:annotation>
      </xsd:enumeration>
      <xsd:enumeration value="3">
        <xsd:annotation>
          <xsd:documentation>Referable Retinopathy</xsd:documentation>
```

```
        </xsd:annotation>
      </xsd:enumeration>
    </xsd:restriction>
  </xsd:simpleType>
  <xsd:simpleType name="MaculopathyType">
    <xsd:restriction base="xsd:positiveInteger">
      <xsd:enumeration value="1">
        <xsd:annotation>
          <xsd:documentation>No Maculopathy</xsd:documentation>
        </xsd:annotation>
      </xsd:enumeration>
      <xsd:enumeration value="2">
        <xsd:annotation>
          <xsd:documentation>Referable Maculopathy</xsd:documentation>
        </xsd:annotation>
      </xsd:enumeration>
    </xsd:restriction>
  </xsd:simpleType>
  <xsd:simpleType name="PresentAbsentType">
    <xsd:restriction base="xsd:integer">
      <xsd:enumeration value="0">
        <xsd:annotation>
          <xsd:documentation>Absent</xsd:documentation>
        </xsd:annotation>
      </xsd:enumeration>
      <xsd:enumeration value="1">
        <xsd:annotation>
          <xsd:documentation>Present</xsd:documentation>
        </xsd:annotation>
      </xsd:enumeration>
    </xsd:restriction>
  </xsd:simpleType>
  <xsd:simpleType name="NormalAbnormalType">
    <xsd:restriction base="xsd:integer">
      <xsd:enumeration value="0">
        <xsd:annotation>
          <xsd:documentation>Abnormal</xsd:documentation>
```

```
        </xsd:annotation>
      </xsd:enumeration>
      <xsd:enumeration value="1">
        <xsd:annotation>
          <xsd:documentation>Normal</xsd:documentation>
        </xsd:annotation>
      </xsd:enumeration>
    </xsd:restriction>
  </xsd:simpleType>
  <xsd:simpleType name="DrugTherapyType">
    <xsd:restriction base="xsd:positiveInteger">
      <xsd:enumeration value="1">
        <xsd:annotation>
          <xsd:documentation>Insulin Only</xsd:documentation>
        </xsd:annotation>
      </xsd:enumeration>
      <xsd:enumeration value="2">
        <xsd:annotation>
          <xsd:documentation>Tablet Only</xsd:documentation>
        </xsd:annotation>
      </xsd:enumeration>
      <xsd:enumeration value="3">
        <xsd:annotation>
          <xsd:documentation>Insulin and Tablets</xsd:documentation>
        </xsd:annotation>
      </xsd:enumeration>
      <xsd:enumeration value="4">
        <xsd:annotation>
          <xsd:documentation>None (Diet Only)</xsd:documentation>
        </xsd:annotation>
      </xsd:enumeration>
    </xsd:restriction>
  </xsd:simpleType>
  <xsd:simpleType name="SelfMonitoringType">
    <xsd:restriction base="xsd:integer">
      <xsd:enumeration value="1">
        <xsd:annotation>
```

```
            <xsd:documentation>Urine</xsd:documentation>
          </xsd:annotation>
        </xsd:enumeration>
        <xsd:enumeration value="2">
          <xsd:annotation>
            <xsd:documentation>Blood Glucose</xsd:documentation>
          </xsd:annotation>
        </xsd:enumeration>
        <xsd:enumeration value="3">
          <xsd:annotation>
            <xsd:documentation>Urine and Blood Glucose</xsd:documentation>
          </xsd:annotation>
        </xsd:enumeration>
      </xsd:restriction>
    </xsd:simpleType>
    <xsd:simpleType name="Weight">
      <xsd:restriction base="xsd:float">
        <xsd:minInclusive value="5"/>
        <xsd:maxInclusive value="300"/>
      </xsd:restriction>
    </xsd:simpleType>
    <xsd:simpleType name="Cigarettes">
      <xsd:restriction base="xsd:integer">
        <xsd:minInclusive value="0"/>
        <xsd:maxInclusive value="100"/>
      </xsd:restriction>
    </xsd:simpleType>
    <xsd:simpleType name="Alcohol">
      <xsd:restriction base="xsd:integer">
        <xsd:minInclusive value="0"/>
        <xsd:maxInclusive value="60"/>
      </xsd:restriction>
    </xsd:simpleType>
    <xsd:simpleType name="Height">
      <xsd:restriction base="xsd:float">
        <xsd:minInclusive value="0.3"/>
        <xsd:maxInclusive value="3"/>
```

```
    </xsd:restriction>
  </xsd:simpleType>
  <xsd:simpleType name="BodyMassIndex">
    <xsd:restriction base="xsd:float">
      <xsd:minInclusive value="0.01"/>
      <xsd:maxInclusive value="100"/>
    </xsd:restriction>
  </xsd:simpleType>
  <xsd:simpleType name="SBP">
    <xsd:restriction base="xsd:integer">
      <xsd:minInclusive value="10"/>
      <xsd:maxInclusive value="400"/>
    </xsd:restriction>
  </xsd:simpleType>
  <xsd:simpleType name="DBP">
    <xsd:restriction base="xsd:integer">
      <xsd:minInclusive value="10"/>
      <xsd:maxInclusive value="300"/>
    </xsd:restriction>
  </xsd:simpleType>
  <xsd:simpleType name="HbA1c">
    <xsd:restriction base="xsd:float">
      <xsd:minInclusive value="2.15"/>
      <xsd:maxInclusive value="25.02"/>
    </xsd:restriction>
  </xsd:simpleType>
  <xsd:simpleType name="Creatinine">
    <xsd:restriction base="xsd:float">
      <xsd:minInclusive value="3"/>
      <xsd:maxInclusive value="1999"/>
    </xsd:restriction>
  </xsd:simpleType>
  <xsd:simpleType name="Cholesterol">
    <xsd:restriction base="xsd:float">
      <xsd:minInclusive value="0.01"/>
      <xsd:maxInclusive value="50"/>
    </xsd:restriction>
```

```
</xsd:simpleType>
<xsd:simpleType name="HDL">
  <xsd:restriction base="xsd:float">
    <xsd:minInclusive value="0.01"/>
    <xsd:maxInclusive value="5"/>
  </xsd:restriction>
</xsd:simpleType>
<xsd:simpleType name="LDL">
  <xsd:restriction base="xsd:float">
    <xsd:minInclusive value="0.01"/>
    <xsd:maxInclusive value="15"/>
  </xsd:restriction>
</xsd:simpleType>
<xsd:simpleType name="Triglycerides">
  <xsd:restriction base="xsd:float">
    <xsd:minInclusive value="0.01"/>
    <xsd:maxInclusive value="100"/>
  </xsd:restriction>
</xsd:simpleType>
<xsd:simpleType name="Injections">
  <xsd:restriction base="xsd:integer">
    <xsd:minInclusive value="0"/>
    <xsd:maxInclusive value="20"/>
  </xsd:restriction>
</xsd:simpleType>
<xsd:simpleType name="DateOfBirth">
  <xsd:restriction base="xsd:date">
    <xsd:minInclusive value="1900-01-01"/>
    <xsd:maxInclusive value="2010-12-12"/>
  </xsd:restriction>
</xsd:simpleType>
<xsd:simpleType name="DateOfDiagnosis">
  <xsd:restriction base="xsd:date">
    <xsd:minInclusive value="1900-01-01"/>
    <xsd:maxInclusive value="2010-12-12"/>
  </xsd:restriction>
</xsd:simpleType>
```

```
  <xsd:simpleType name="EpisodeDate">
    <xsd:restriction base="xsd:date">
      <xsd:minInclusive value="1900-01-01"/>
      <xsd:maxInclusive value="2010-12-12"/>
    </xsd:restriction>
  </xsd:simpleType>
  <xsd:simpleType name="ActivityStartDate">
    <xsd:restriction base="xsd:date">
      <xsd:minInclusive value="1900-01-01"/>
      <xsd:maxInclusive value="2010-12-12"/>
    </xsd:restriction>
  </xsd:simpleType>
  <xsd:simpleType name="ActivityEndDate">
    <xsd:restriction base="xsd:date">
      <xsd:minInclusive value="1900-01-01"/>
      <xsd:maxInclusive value="2010-12-12"/>
    </xsd:restriction>
  </xsd:simpleType>
</xsd:schema>
```