**Revised Annex A and B, as of 25 April 2013, amending Annex A and B in “epSOS Response on Patient Summary Dataset”, dated 13 February 2013**

**ANNEX A – PATIENT SUMMARY: DATASET AGREED IN THE CLINICAL GROUP**

| **PATIENT DATA** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **VARIABLE (nesting level 1)** | **VARIABLES**  **(nesting level 2)** | **VARIABLES**  **(nesting level 3)** | **DEFINITION AND COMMENTS** | **BASIC (Basic)/EXTENDED (Ext) DATASET** | **MANDATORY Yes/No** |
| **Identification [[1]](#footnote-1)** | National Health Care patient ID | National Health Care patient ID | Country ID, unique for the patient in that country. Example: ID for United Kingdom patient | Basic | Yes |
| **Personal information** | Full Name | Given name | The Name of the patient (Example: John). This field can contain more than one element | Basic | Yes |
| Family name/Surname | This field can contain more than one element. Example: Español Smith | Basic | Yes |
| Date of Birth | Date of Birth | This field may contain only the year[[2]](#footnote-2) if day and month are not available. Eg: 01/01/2009 | Basic | Yes |
| Gender | Gender Code | It must contained a recognized valid value for this field | Basic | Pending decision by WP3.6 (in some countries ‘gender’ is needed for univocal identification of the patient) |
| **Contact information** | Address[[3]](#footnote-3) | Street | Example: Oxford | Ext | No |
| Number of Street | Example: 221 | Ext | No |
| City | Example: London | Ext | No |
| Post Code | Example: W1W 8LG | Ext | No |
| State or Province | Example: London | Ext | No |
| Country | Example: UK | Ext | No |
| Telephone No | Telephone No | Example: +45 20 7025 6161 | Ext | No |
| E-mail | E-mail | Example: jens@hotmail.com | Ext | No |
| Preferred HCP/Legal organization to contact[[4]](#footnote-4) | Name of the HCP/Legal organization | Name of the HCP/name of the legal organization. If it is a HCP, the structure of the name will be the same as described in ‘Full name’ (Given name, family name/surname) | Basic | No |
| Telephone No | Example: +45 20 7025 6161 | Basic | No |
| E-mail | E mail of the HCP/legal organization | Basic | No |
|  | Contact Person/ legal guardian  (if available) | Role of that person | Legal guardian or Contact person | Ext | NO |
|  |  | Given name | The Name of the Contact Person/guardian (example: Peter. This field can contain more than one element) | Ext | No |
|  |  | Family name/Surname | This field can contain more than one element. Example: Español Smith | Ext | No |
|  |  | Telephone No | Example: +45 20 7025 6161 | Ext | No |
|  |  | E-mail |  | Ext | No |
| **Insurance information** | Insurance Number | Insurance Number | Example: QQ 12 34 56 A | Pending decision by WP3.6 of including it in Basic (in some countries ‘Insurance Number’ is needed for univocal identification of the patient). | Pending decision by WP3.6 of including it in Basic (in some countries ‘Insurance Number’ is needed for univocal identification of the patient). |

| **PATIENT CLINICAL DATA** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **VARIABLE (nesting level 1)** | **VARIABLES (nesting level 2)** | **VARIABLES (nesting level 3)** | **COMMENTS** | **BASIC (Basic)/EXTENDED (Ext) DATASET** | **MANDATORY Yes/No** |
| **Alerts** | Allergies and intolerancess | Allergy description | Description of the clinical manifestation of the allergy reaction. Example: Anaphylactic shock, angioedema (the clinical manifestation also gives information about the the severity of the observed reaction) | Basic | No |
| Allergy description id code | Normalized identifier | Basic | No |
| Onset Date | Date of the observation of the reaction | Ext | No |
| Agent | Describes the agent (drug, food, chemical agent, etc) that is responsible for the adverse reaction | Basic | No |
| Agent id code | Normalized identifier | Basic | No |
| **History of past illness** | Vaccinations | Vaccinations | Contains each disease against which immunization was given | Ext | No |
| Brand name |  | Ext | No |
| Vaccinations id code | Normalized identifier | Ext | No |
| Vaccination Date | The date the immunization was received | Ext | No |
| List of Resolved, Closed or Inactive problems | Problem Description | Problems or diagnosis not included under the definition of ‘Current problems or diagnosis’. Example: hepatic cyst (the patient has been treated with an hepatic cystectomy that solved the problem and therefore it´s a closed problem) | Ext | No |
| Problem Id (code) | Normalized identifier | Ext | No |
| On set time | Date of problem onset | Ext | No |
| End date | Problem resolution date | Ext | No |
| Resolution Circumstances | Describes the reason by which the problem changed the status from current to inactive (e.g. surgical procedure, medical treatment, etc). This field includes ‘free text’ if the resolution circumstances are not already included in other fields. Example: It can happen that this field is already included in other like Surgical Procedure, medical device etc, eg: hepatic cystectomy (this wil be the ‘Resolution Circumstances’ for the problem ‘hepatic cyst’ and will be included in surgical procedures) | Ext | No |
| Surgical Procedures prior to the past six months | Procedure description | Describes the type of procedure | Ext | No |
| Procedure Id (code) | Normalized identifier | Ext | No |
| Procedure date | Date when procedure was performed | Ext | No |
| **Medical problems** | List of Current Problems/Diagnosis. | Problem/diagnosis description | Problems/diagnosis that fit under these conditions: conditions that may have a chronic or relapsing course (eg: exacerbations of asthma, irritable bowel syndrome), conditions for which the patient receives repeat medications (eg: diabetes mellitus, hypertension) and conditions that are persistent and serious contraindications for classes of medication (eg: dyspepsia, migraine and asthma) | Basic | No |
| Problem Id (code) | Normalized identifier | Basic | No |
| Onset time | Date of problem onset | Basic | No |
| Medical Devices and implants | Device and implant Description | Describes the patient’s implanted and external medical devices and equipment that their health status depends on. Includes devices as cardiac pacemakers, implantable defibrillator, prothesis, ferromagnetic bone implants etc that are important to know by the HCP | Basic | No |
| Device Id code | Normalized identifier | Basic | No |
| Implant date |  | Basic | No |
| Major Surgical Procedures in the past 6 months[[5]](#footnote-5) | Procedure description | Describes the type of procedure | Basic | No |
| Procedure Id (code) | Normalized identifier | Basic | No |
| Procedure date | Date when procedure was performed | Basic | No |
| Treatment Recommendations | Recommendations Description | Therapeutic recommendations that do not include drugs (diet, physical exercise constraints, etc.) | Ext | No |
| Recommendation Id (code) | Normalized identifier | Ext | No |
| Autonomy/Invalidity | Description | Need of the patient to be continuously assisted by third parties. Invalidity status may influence decisions about how to administer treatments | Ext | No |
| Invalidity Id code | Normalized invalidity ID (if any, otherwise free text) | Ext | No |
| **Medication Summary** | List of current medicines.  (All prescribed medicine whose period of time indicated for the treatment has not yet expired whether it has been dispensed or not.). | Active ingredient | Substance that alone or in combination with one or more other ingredients produces the intended activity of a medicinal product. Example: Paracetamol | Basic | No |
| Active ingredient id code | Code that identifies the Active ingredient | Basic | No |
| Strength | The content of the active ingredient expressed quantitatively per dosage unit, per unit of volume or per unit of weight, according to the pharmaceutical dose form. Example: 500 mg per tablet | Basic | No |
| Pharmaceutical dose form | It is the form in which a pharmaceutical product is presented in the medicinal product package (e.g. tablets, syrup) | Ext | No |
| Number of units per intake[[6]](#footnote-6) | The number of units per intake that the patient is taking. Example: 1 tablet | Basic | No |
| Frequency of intakes | Frequency of intakes (per hours/day/month/ week..). Example: each 24 hours | Basic | No |
| Duration of treatment10 | Example: during 14 days | Basic | No |
| Date of onset of treatment | Date when patient needs to start taking the medicine prescribed | Basic | No |
| **Social History** | Social History Observations | Social History Observations related to: smoke, alcohol and diet. | Example: cigarette smoker, alcohol consumption... | Ext | No |
| Reference date range | Example: from 1974 thru 2004 | Ext | No |
| **Pregnancy History** | Expected date of delivery | Expected date of delivery | Date in which the woman is due to give birth. Year, day and month are required. Eg: 01/01/2010 | Ext | No |
| **Physical findings** | Vital Signs Observations | Blood pressure | One value of blood pressure which includes: systolic Blood Pressure and Diastolic Blood pressure | Ext | No |
| Date when blood pressure was measured | Date when blood pressure was measured | Ext | No |
| **Diagnostic tests** | Blood group | Result of blood group | Result from the blood group test made to the patient | Ext | No |
| Date | Date in which the blood group test was done. This field may contain only the year if day and month are not available. Eg: 01/01/2009 | Ext | No |

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| **PATIENT SUMMARY DATA**  **(Information about the PS itself)** | | | | | |
| **VARIABLE (nesting level 1)** | **VARIABLES (nesting level 2)** | **VARIABLES (nesting level 3)** | **COMMENTS** | **BASIC (Basic)/EXTENDED (Ext) DATASET** | **MANDATORY Yes/No** |
| **Country** | Country | Country | Name of country A | Basic | Yes |
| **Patient Summary** | Date Created | Date Created | Data on which PS was generated | Basic | No |
| Date of Last Update | Date of Last Update | Data on which PS was updated (data of last version) | Basic | Yes |
| Author/Nature of the patient summary | Author of the patient summary | Author of the patient summary | To highlight if the data is collected manually by an HCP or is collected automatically form different sources (eg: hospital doctor repository, GPs…etc) through predetermine clinical rules. | Basic | No |
| **Legal entity** | Responsible of the PS data | Responsible of the PS data | At least an author organization (HCPO) shall be listed. In case there is not HCPO identified at least a HCP shall be listed | Basic | No |

**ANNEX B – SUMMARY OF THE MAIN TERMINOLOGIES CHOSEN**

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| --- | --- |
| **FIELD** | **TERMINOLOGY CHOSEN** |
| Field Labels | LOINC |
| Problem list | ICD 10 (3 digits code) |
| Medication list | ATC + EDQM + UCUM |
| Allergies | SNOMED |
| Surgical procedures | SNOMED |
| Medical devices | SNOMED |
| Country and languages | ISO |
| Professional role | ISCO |

1. Data set that enable the univocal identification of the patient. It will be defined in WP3.6 ‘Identity Management’. The variable ‘Birth place’ (Country of birth and place of birth) needs to be evaluated by WP3.6 as in some countries it is needed for univocal identification of the patient. [↑](#footnote-ref-1)
2. To be aligned with prescription minimum dataset (in D3.1.2 ‘Final definition of functional service requirements-ePrescription’) [↑](#footnote-ref-2)
3. Will be adapted due to the variability of the countries. [↑](#footnote-ref-3)
4. A foreign HCP may need a contact (HCP/legal organization) who knows the patient [↑](#footnote-ref-4)
5. As there is subjectivity in the term ‘relevant’, the date will be used as the limit to include procedures. [↑](#footnote-ref-5)
6. Posology has been defined from the functional point of view as containing these three components: number of units per intake, frequency of intakes and duration of treatment:(example: 1 unit/intake every 24 hours for a duration of 14 days [↑](#footnote-ref-6)