

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	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 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	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	

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.

² To be aligned with prescription minimum dataset (in D3.1.2 ‘Final definition of functional service requirements-ePrescription’)

³ Will be adapted due to the variability of the countries.

	Preferred HCP/Legal organization to contact 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).

⁴ A foreign HCP may need a contact (HCP/legal organization) who knows 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 intolerances	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	Ext	No

PATIENT CLINICAL DATA					
VARIABLE (nesting level 1)	VARIABLES (nesting level 2)	VARIABLES (nesting level 3)	COMMENTS	BASIC (Basic)/EXTENDED (Ext) DATASET	MANDATORY Yes/No
			Procedure, medical device etc, eg: hepatic cystectomy (this will be the 'Resolution Circumstances' for the problem 'hepatic cyst' and will be included in surgical procedures)		
	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, prosthesis, 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	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

⁵ As there is subjectivity in the term 'relevant', the date will be used as the limit to include procedures.

PATIENT CLINICAL DATA					
VARIABLE (nesting level 1)	VARIABLES (nesting level 2)	VARIABLES (nesting level 3)	COMMENTS	BASIC (Basic)/EXTENDED (Ext) DATASET	MANDATORY Yes/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	The number of units per intake that the patient is taking. Example: 1 tablet	Basic	No
		Frequency of intakes ⁶	Frequency of intakes (per hours/day/month/ week..). Example: each 24 hours	Basic	No
		Duration of treatment ⁶	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	Expected date of	Expected date of delivery	Date in which the woman is due to give	Ext	No

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

PATIENT CLINICAL DATA					
VARIABLE (nesting level 1)	VARIABLES (nesting level 2)	VARIABLES (nesting level 3)	COMMENTS	BASIC (Basic)/EXTENDED (Ext) DATASET	MANDATORY Yes/No
History	delivery		birth. Year, day and month are required. Eg: 01/01/2010		
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

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 from 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

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