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ICMRA - Mapping of IT initiatives as a support to global medicines regulation

	Initiative	Objectives related to IT Medicines initiatives	Scope	Membership	Work Products	Contact Point
1	**International Organization for Standardization (ISO) identification of medicinal products (IDMP) standards**	This initiative aims to use common standards, formats and terminologies internationallyto identify and exchange pharmacovigilance and medicinal product information amongst regulatory authorities.	Medicinal products	119 member bodies: Afghanistan; Algeria; Argentina; Armenia; Australia; Austria; Azerbaijan; Bahrain; Bangladesh; Barbados; Belarus; Belgium; Benin; Bosnia and Herzegovina; Botswana; Brazil; Bulgaria;; Burkina Faso; Cameroon; Canada; Chile; China; Colombia; Congo, The Democratic Republic of the; Costa Rica; Côte d'Ivoire; Croatia; Cuba; Cyprus; Czech Republic; Denmark; Ecuador; Egypt; El Salvador; Estonia; Ethiopia; Fiji; Finland; France; Gabon; Germany; Ghana; Greece; Hungary; Iceland; India; Indonesia; Iran, Islamic Republic of; Iraq; Ireland; Israel; Italy; Jamaica; Japan; Jordan; Kazakhstan; Kenya; Korea, Democratic People's Republic of; Korea, Republic of; Kuwait; Latvia; Lebanon; Libya; Lithuania; Luxembourg; Malawi; Malaysia; Mali; Malta; Mauritius; Mexico; Mongolia; Morocco; Namibia; Nepal; Netherlands; New Zealand; Nigeria; Norway; Oman;; Pakistan; Panama; Peru; Philippines; Poland; Portugal; Qatar; Romania; Russian Federation; Rwanda; Saint Lucia; Saudi Arabia; Senegal; Serbia; Singapore; Slovakia; Slovenia; South Africa; Spain; Sri Lanka; Sudan; Sweden; Switzerland; Tanzania, United Republic of; Thailand; The Former Yugoslav Republic of Macedonia; Trinidad and Tobago; Tunisia; Turkey; Uganda; Ukraine; United; Arab Emirates; United Kingdom; United States; Uruguay; Uzbekistan; Viet Nam; Yemen; Zimbabwe 40 Correspondent members: Albania; Angola; Bahamas; Bhutan; Bolivia, Plurinational State of; Brunei Darussalam; Burundi; Cambodia; Dominica; Dominican Republic; Eritrea; Gambia; Georgia; Guatemala; Guyana; Haiti; Honduras; Hong Kong; Kyrgyzstan; Lesotho; Macao; Madagascar; Mauritania; Moldova, Republic of; Montenegro; Mozambique; Myanmar; Nicaragua; Niger; Palestine, State of; Papua; New Guinea; Paraguay; Saint Kitts and Nevis; Seychelles; Sierra Leone; Suriname; Swaziland; Tajikistan; Turkmenistan; Zambia 4 subscribers members: Antigua and Barbuda; Belize; Lao People's Democratic Republic; Saint Vincent and the Grenadines	1. ISO prEN 11238, Health Informatics, Identification of Medicinal Products (IDMP) standard 'Data elements and structures for unique identification and exchange of regulated information on substances' Draft update of the standard planned for December 2015 Publication planned for July 2016 2. ISO prEN 11239, Health Informatics, Identification of Medicinal Products (IDMP) standard 'Data elements and structures for unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging' Final and stable standard sa of October 2015 3. ISO prEN 11240, Health Informatics, Identification of Medicinal Products (IDMP) standard 'Data elements and structures for unique identification and exchange of units of measurement' Final and stable standard sa of October 2015 4. ISO prEN 11615, Health Informatics, Identification of Medicinal Products (IDMP) standard 'Data elements and structures for unique identification and exchange of regulated medicinal product information' Draft update of the standard planned for December 2015 Publication planned for July 2016 5. ISO prEN 11616, Health Informatics, Identification of Medicinal Products (IDMP) standard 'Data elements and structures for unique identification and exchange of regulated pharmaceutical product information' Draft update of the standard planned for December 2015 Publication planned for July 2016 6. Regional implementation guides: • ISO prEN 11238 Substance (Core + 4 annexes): Final and stable guide Final and stable guide • ISO prEN 11238 Substance (Remaining 6 annexes) Draft update planned in November 2015 and publication in July 2016 •ISO prEN 11239 Dose, pres. units, routes, packaging Draft update planned in November 2015 and publication in July 2016 •ISO prEN 11615 Medicinal Product Draft update planned in November 2015 and publication in July 2016 •ISO prEN 11616 Pharmaceutical Product Draft update planned in November 2015 and publication in July 2016 7. HL7 Messaging Formats •Substance: Publication in October 2015 • Product: Publication in October 2015 8. Maintenance arrangements under discussion (FDA/EMA)	art57@ema.europa.eu
2	**MedDRA Medical Dictionary for Regulatory Activities**	To adopt a dedicated single standardised terminology offering a number of clear advantages for regulators, industry and other stakeholders including healthcare professionals, patients and research organisations	Registration, documentation and safety monitoring of medicinal products through all phases of the development cycle	Founding members: European Union (EU) European Federation of Pharmaceutical Industries and Associations (EFPIA) Labour and Welfare (MHLW) Japan Pharmaceutical Manufacturers Association (JPMA) Food and Drug Administration (FDA) Pharmaceutical Research and Manufacturers of America (PhRMA) Observers: European Free Trade Association (EFTA), Health Canada, and the World Health Organization (WHO)	1. Removal of the need to convert data from one terminology to another preventing the loss and/or distortion of data and allowing savings in resources 2. Facilitation of the electronic exchange of data relating to medicinal products 3. Improvements in the ease, quality and timeliness of data available for effective analysis, exchange and decision making 4. Consistency of the terminology throughout the different stages of the development of a medicinal product allowing effective cross-references and analysis of data	mssohelp@meddra.org
3	**CDISC Clinical Data Interchange Standards Consortium**	To develop freely available, industry-wide clinical research data standards	Clinical research	http://www.cdisc.org/our-members	1. Promote and support the continued global adoption of harmonized data standards throughout the clinical research lifecycle by engaging regulatory agencies, research sponsors, academia and other stakeholders through education, advocacy and collaboration. 2. Implement clinical research standards that are complementary to standards in the broader healthcare ecosystem and thus add value for clinical researchers, healthcare providers and patients. 3. Leverage the Shared Health And Research Electronic Library (SHARE) and other tools to further expedite the development and facilitate the implementation of harmonized standards for clinical research.	info@cdisc.org

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4	**Unique Facility Identifier**	Establishment of a common unique identifier system for facilities to be used by all ICMRA members	Manufacturers of medicinal products and active substances (drug products and drug substances)	N/A Current discussion at ICMRA, PIC/S and EMA FDA has published a draft guidance http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm367199.pdf	Common global Unique Facility Identifiers (Currently, the FDA proposes the Data Universal Numbering System (DUNS) number as appropriate to meet Agency needs for a data standard for drug establishment registration UFI, but this is not approved.)	eDRLS@fda.hhs.gov
5	**PAHO's Regional Platform on Access and Innovation for Health Technologies** **PRAISSec**	1. Supports the exchange of documents resulting from regulatory processes between Regional NRAs and/or Regional NRAs with NRAs from other Regions 2. The exchange of GMP inspection reports is being used as a way to model and pilot this tool on its initial stage.	Web based virtual tools for: • Regulatory indicators • Annotated Medicines Lists • Repositories • Communities of Practice • Supply Management Tools	Working group: The Agência Nacional de Vigilância Sanitária (ANVISA, Brazil), The US Food and Drug Administration (FDA), Health Canada and The Comisión Federal para la Protección contra Riesgos; Sanitarios (COFEPRIS, Mexico) Partner: World Health Organisation (WHO)	Secure web- based platform for the exchange of Regulatory information. First model: GMP Inspection Reports	N/A
6	**ICH guideline E2B (R3) on electronic transmission of individual case safety reports (ICSRs) - data elements and message specification - implementation guide**	To standardise the definition of the data elements used in the electronic transmission of different types of ICSRs, regardless of source and destination.	The scope of this IG for the ICH E2B (R3) ICSR does not include the definition of database structures, the design of a paper report form, quality control/quality assurance aspects, or technical security issues	ICH members: Founding Regulatory Members: The European Commission (EC); The US Food and Drug Administration (FDA); The Ministry of Health, Labour and Welfare of Japan (MHLW) also represented by the Pharmaceuticals; Medical Devices Agency (PMDA) Founding Industry Members: The European Federation of Pharmaceutical Industries and Associations (EFPIA); The Japan Pharmaceutical Manufacturers Association (JPMA); The Pharmaceutical Research and Manufacturers of America (PhRMA) Standing Regulatory Members: The Health Canada; The Swissmedic Industry Members: The International Generic and Biosimilar Medicines Association (IGBA); The World Self-Medication Industry (WSMI) Standing Observers: The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA); The World Health Organisation (WHO) Observers: Legislative or Administrative Authorities The Agência Nacional de Vigilância Sanitária (ANVISA, Brazil); The Central Drugs Standard; Control Organization (CDSCO, India); The Comisión Federal para la Protección contra Riesgos; Sanitarios (COFEPRIS, Mexico); The Health Sciences Authority (HSA, Singapore); The Ministry of Food and Drug Safety (MFDS, South Korea); The Roszdravnadzor (Russia); The Food and Drug Administration (TFDA, Chinese Taipei); The Therapeutic Goods Administration (TGA, Australia) Regional Harmonisation Initiatives (RHIs): The Asia-Pacific Economic Cooperation (APEC); The Association of Southeast Asian Nations (ASEAN); The East African Community (EAC); The Gulf Cooperation Council (GCC); The Pan American Network for Drug Regulatory Harmonization (PANDRH); The Southern African Development Community (SADC) International Pharmaceutical Industry Organisations: The Biotechnology Innovation Organisation (BIO) International Organisations with an Interest in Pharmaceuticals: The Council for International Organizations of Medical Sciences (CIOMS); The European Directorate for the Quality of Medicines & HealthCare (EDQM); The International Pharmaceutical Excipient Council (IPEC); The United States Pharmacopeia (USP)	1. ICH E2B Individual Case Safety Report (ICSRs) 2. Implementation guide	admin@ich.org
7	**CEN** **European Committee for Standardisation**	To develop European Standards (ENs)	Medicinal products	28 EU Member States: Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the UK. 3 EFTA Members: Iceland, Norway, Switzerland 2 Other Members: Macedonia and Turkey	1. Technical Committees 2. Subcommittes 3. Working Groups	http://www.cen.eu/helpers/Pages/contactus.aspx

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8	**EUDRAGMDP Database**	To share information on manufacturing, import and wholesale-distribution authorisations, and good manufacturing-practice (GMP) and good-distribution-practice (GDP) certificates.	Medicinal products	Full right access: EEA Members (28 EU + EFTA) Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the UK. Iceland, Norway, Switzerland Other authorities who can upload GMP certificates and non-compliance reports into EudraGMDP: Therapeutic Goods Administration (TGA, Australia); Australian Pesticides and Veterinary Medicines Authority (APVMA, Australia); Health Canada (Canada); Institute for Standardization and Control of Pharmaceuticals, Ministry of Health (ISCP, Israel) ; Swissmedic (Switzerland); Ministry of Health, Labour and Welfare (MHLW, Japan); Ministry of Health (MOH, New Zealand); Ministry of Agriculture and Forestry (MAF, New Zealand), which includes New Zealand Food Safety Authority (NZFSA, New Zealand)	1. Public database 2. Members database including commercially or personally confidential information	eudragmdp@ema.europa.eu
9	**EudraCT European Union Drug Regulatory Authorities Clinical Trials**	To harmonise the submission and implementation of clinical trials.	Clinical trials with at least one site in the European Union	EU Member States: Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, UK	1. European Clinical Trials Database of all clinical trials of investigational medicinal products with at least one site in the European Union commencing 1 May 2004 or later 2. Unique EudraCT Number 3. Read guidance on EudraCT application 4. Download editable forms 5. Complete EudraCT clinical trial application form and save as XML or PDF locally	EudraCT@ema.europa.eu
10	**IHTSDO International Health Terminology Standards Development Organization**	To develop a global language for health, uniting health systems from around the world and enabling them to communicate with and understand one another	Health standards	Australia, Belgium, Brunei, Canada, Chile, Czech Republic, Denmark, Estonia, Hong Kong, Iceland, India, Israel, Lithuania, Malaysia, Malta, Netherlands, New Zealand, Poland, Portugal, Singapore, Slovak Republic, Republic of Slovenia, Spain, Sweden, United Kingdom, United States, Uruguay	1. Joint planning sessions with the Management Board and General Assembly 2. Consultations with members of IHTSDO"s General Assembly, Standing Committees, the Member Forum, the Affiliate Forum, and others 3. A focus group with users of SNOMED CT 4. Invitations to comment issued to the global Community of Practice as a whole	info@ihtsdo.org

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The information on this table has been compiled by EMA according to the available information.
As in certain cases it is difficult to have accurate or up-to-date information and rhere are continuous changes, EMA strongly recommends to check the iformation with the relevant websites or directly with the relevant organisations.