ADVERSE REACTION RISK(FHIR/openEHR)

HEADER

Archetype ID	openEHR-EHR-EVALUATION.adverse_reaction_fhir.v1
Concept name	Adverse Reaction Risk(FHIR/openEHR)
Concept description	Risk of harmful or undesirable, physiological response which is unique to an individual and associated with exposure to a substance. Comment: Substances include, but are not limited to: a therapeutic substance administered correctly at an appropriate dosage for the individual; food; material derived from plants or animals; or venom from insect stings.
Keywords	reaction, allergy, allergic, adverse, event, effect, sensitivity, intolerance, hypersensitivity, side effect, toxicity, interaction, drug, food, medication, agent, substance, immune, non-immune, chemical
Purpose	To record a clinical assessment of a propensity, or potential risk to an individual, of an adverse reaction upon future exposure to the specified substance, or class of substance. Where a propensity is identified, to record information or evidence about a reaction event that is characterised by any harmful or undesirable, physiological response that is unique to the individual, and triggered by exposure of an individual to the identified substance or class of substance.
Use	Use to provide a single place within the health record to document a range of clinical statements about adverse reactions, including: - record a clinical assessment of the individual's propensity to a potential future reaction upon re-exposure; and - record cumulative information about the reaction to each exposure, including 'no reaction' if appropriate. Use to record information about the positive presence of the risk of an adverse reaction: - to support direct clinical care of an individual; - as part of a managed adverse reaction or allergy/intolerance list; - to support exchange of information about the propensity and events related to adverse reactions; - to inform adverse reaction reporting; and - to assist computerised knowledge-based activities such as clinical decision support and alerts. Use to record information about adverse reactions to a broad range of substances, including: biological & blood products; incipients and excipients in medicinal preparations; metal salts; and organic chemical compounds. Adverse reactions may be: - an immune mediated reaction - Types I-VI (including allergic reactions and hypersensitivities); or - a non-immune mediated reaction - including pseudo-allergic reactions, side effects, intolerances, drug toxicities (eg to Gentamicin), drug-drug interactions, food-drug interactions, and drug-disease interactions. In clinical practice distinguishing between immune-mediated and non-immune mediated reactions is difficult and often not practical. Identification of the type of reaction is not a proxy for seriousness or risk of harm to the patient, which is better expressed by the manifestation in clinical practice. The risk of an adverse reaction event or manifestation should not be recorded without identifying a proposed causative substance or class of substance. If there is uncertainty that a specific substance is the cause, this uncertainty can be recorded using the 'Status' data element. If there are multiple possible substances that may have caused a reaction/manifestation, each substance should be recorded using a separate instance of this adverse reaction archetype/FHIR resource with the 'Status' set to an initial state of 'Unconfirmed' so that adverse reaction checking can be supported in clinical systems. If a substance, agent or class is later proven not to be the cause for a given reaction then the 'Status' can be modified to 'Refuted'. This archetype/FHIR resource has been designed to allow recording of information about a specific substance (amoxycillin, oysters, or bee sting venom) or, alternatively, a class of substance (eg Penicillins)). If a class of substance is recorded then identification of the exact substance can be recorded on a per exposure basis. The scope of this archetype/FHIR resource has deliberately focused on identifying a pragmatic data set that are used in most clinical systems or will be suitable for most common clinical scenarios, however it permits extension of the model when additional detail is required, for example 'Reaction details', 'Exposure details', and 'Reporting details' slots. Examples of clinical situations where the extension may be required include: a detailed allergist/immunologist assessment, for reporting to regulatory bodies or use in a clinical trial. The act of recording any adverse reaction in a health record involves the clinical assessment that a potential hazard exists for an individual if they are exposed to the same substance/agent/class in the future – that is, a relative contraindication - and the default 'Criticality' value should be set to 'Low risk'. If a clinician considers that it is not safe for the individual to be deliberately re-exposed to the substance/agent again, for example, following a manifestation of a life-threatening anaphylaxis, then the 'Criticality' data element should be amended to 'High risk'. A formal Adverse Event Report to regulatory bodies is a document that will contain a broad range of information in addition to the specific details about the adverse reaction. The report could utilise parts of this Risk of adverse reaction archetype/FHIR resource plus include additional data as required per jurisdiction. An adverse reaction or allergy/intolerance list is a record of all identified propensities for an adverse reaction for the individual upon future exposure to the substance or class, plus provides potential access to the evidence provided by details about each reaction event, such as manifestation. Valuable first-level information that could be presented to the clinician when they need to assess propensity for future reactions are: - statements about previous clinical manifestations following exposure; - source of the information/reporter; and - the 'Criticality' flag. Second-level information can be drawn from each exposure event and links to additional detailed information such as history, examination and diagnoses stored elsewhere in the record, if it is available. openEHR only: Links to other parts of the health record where further details may be located, such as consultation notes, is allowed by the openEHR reference model, but not modelled explicitly in this archetype.
Misuse	Not to be used for recording physiological reactions to physical agents, such as heat, cold, sunlight, vibration, exercise activity, by infectious agents or food contaminants. Use archetypes/FHIR resources for Problem/Diagnosis (openEHR) or Conditions (FHIR). Not to be used to record adverse events, including failures of clinical process, interventions or products. For example: abnormal use or mistakes/errors made in maladministration of an agent or substance; incorrect dosage; mislabelling; harm or injury caused by an intervention or procedure; overdose/poisoning etc.

	Not to be used as a proxy for an Adverse Event Report. See above for how it may be used as one component of an Adverse Event Report.

Not to be used for recording alerts.

Not to be used for recording failed therapy.

openEHR only: Not to be used for the explicit recording of an absence (or negative presence) of a reaction to 'any substances' or to identified substances, for example 'No known allergies or adverse reactions' or 'No known allergies to Penicillin'. Use the EVALUATION. exclusion-adverse_reaction archetype to express a positive statement of adverse reaction exclusion.

openEHR only: Not to be used for the explicit recording that no information was able to be obtained about the adverse reaction status of a patient. Use the EVALUATION.absence archetype to record that a positive statement that information was not able to be obtained, for example, if a non-cooperative patient refuses to answer questions. |
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- Uppsala Monitoring Centre (WHO): http://www.who-umc.org/

- European Medicines Agency: http://www.ema.europa.eu/ema/

- DIRECTIVE 2010/84/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, of 15 December 2010, amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use: http://ec.europa.eu/health/files/eudralex/vol-1/dir_2010_84/dir_2010_84_en.pdf

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DATA

Structure: Tree Mandatory (1..1) Cardinality: repeating, unordered (*2..**)		
Substance T Text Mandatory (1..1)	Identification of a substance, or a class of substances, that is considered to be responsible for the adverse reaction. Comment: The Substance field allows for the use of a either specific substance (for example 'Amoxycillin') or a group or class of substances (for example 'Penicillins'). Duplication in the 'Substance' and 'Specific substance' fields is acceptable if clinically appropriate. It is strongly recommended that both 'Substance' and 'Specific substance' be coded with a terminology capable of triggering decision support, where possible. For example: including but not limited to RxNorm, Snomed CT, DM+D, NDFRT, ICD-9, IDC-10, UNI, ATC and CPT. Plain text should be used only if there is no appropriate terminology available. **source:** openEHR,FHIR,DAM	
Status T Coded Text Optional (0..1)	Assertion about the propensity, or potential risk, of a reaction to the identified 'Substance'. Comment: Decision support would typically raise alerts for 'Unconfirmed', 'Confirmed', and 'Resolved' and ignore a 'Refuted' reaction. In particular, 'Refuted' may be useful for reconciliation of the adverse reaction list. Some implementations may choose to make this field mandatory. **source:** FHIR,DAM	• **Unconfirmed** [A low level of certainty about the propensity for a reaction to the identified 'Substance'.] • **Confirmed** [A high level of certainty about the propensity for a reaction to the identified 'Substance', which may include clinical evidence by testing or re-challenge.] • **Resolved** [A previously known reaction to the identified 'Substance' has been clinically reassessed by testing and/or re-challenge and considered no longer to be an active risk.] • **Refuted** [A propensity for a reaction to the identified 'Substance' has been reassessed by testing and/or re-challenge, and has been disproved with a high level of clinical certainty.] Possible reasons why null: • unknown
Criticality T Coded Text Optional (0..1)	Estimate of the potential clinical harm, or seriousness, of the reaction to the identified 'Substance'. Comment: The default Criticality value for	• **Low risk** [The potential clinical impact of a future reaction is estimated as low risk. Future exposure to the identified

	any propensity to an adverse reaction should be 'Low risk', indicating at the very least a relative contraindication to deliberate or voluntary exposure to the identified 'Substance'. 'High risk' is flagged if the clinician has identified a propensity for a more serious or potentially life-threatening reaction, such as anaphylaxis, and implies an absolute contraindication to deliberate or voluntary exposure to the substance. **source:** DAM, openEHR	'Substance' is considered a relative contra-indication.] • **High risk** [The potential clinical impact of a future reaction is estimated as high risk. Future exposure to the identified 'Substance' may be considered an absolute contra-indication.]
Reaction type **T** Coded Text Optional (0..1)	Identification of the underlying physiological mechanism for the adverse reaction. Comment: Immune-mediated responses have been traditionally regarded as an indicator for escalation of significant future risk. Contemporary knowledge suggests that some reactions previously thought to be immune and non-immune and still carry life threatening risk. It is acknowledged that many clinicians may not be in a position to distinguish the mechanism of a particular reaction. This data element is included nevertheless because many legacy systems have captured this attribute. Immunological testing may provide supporting evidence for the basis and causative substance , but no tests are 100% sensitive or specific for a sensitivity. **source:** FHIR,DAM	• **Immune mediated** [Immune mediated reaction, including allergic reactions and hypersensitivities.] • **Non-immune mediated** [A non-immune mediated reaction, which can include pseudo-allergic reactions, side effects, intolerances, drug toxicities (for example, to Gentamicin), drug-drug interactions, food-drug interactions, and drug-disease interactions.] Possible reasons why null: • unknown
Substance category **T** Coded Text Optional (0..1)	Category of the identified 'Substance'. Comment: This data element has been included because it is currently being captured in some clinical systems. This data can be derived from the Substance where coding systems are used, and is effectively redundant in that situation.	• **Food** [Any substance consumed to provide nutritional support for the body.] • **Medication** [Any substance administered to achieve a physiological effect.] • **Environment** [Any substance encountered in the environment.]
Date of last reaction Date/Time Optional (0..1)	Represents the date and/or time of the last known occurrence of a reaction event. Comment: This date may be replicated by one of the Onset of Reaction dates. Where a textual representation of the date of last occurrence is required e.g 'In Childhood, '10 years ago' the Comment element should be used. **source:** IMH	
Comment **T** Text Optional (0..1)	Additional narrative about the propensity for the adverse reaction, not captured in other fields. Comment: For example: including reason for flagging a 'Criticality' of 'High risk'; and instructions related to future exposure or administration of the Substance, such as administration within an Intensive Care Unit or under corticosteroid cover. **source:** openEHR	
Reaction event Cluster Optional, repeating (0..*) Cardinality: Mandatory, repeating, unordered (*1..**)	Details about each adverse reaction event linked to exposure to the identified 'Substance'. **source:** openEHR,FHIR,DAM	
Specific substance **T** Text Optional (0..1)	Identification of the specific substance considered to be responsible for the adverse reaction event. Comment: For example: 'Amoxycillin'. Duplication of the value recorded in the 'Substance' and 'Specific substance' fields is acceptable if clinically appropriate. It is strongly recommended that 'Specific substance' be coded with a terminology capable of triggering decision support, where possible. For example: including but not limited to RxNorm, Snomed CT, DM+D, NDFRT, ICD-9, IDC-10, UNI, ATC and CPT. Plain text should be used only if there is no appropriate terminology available. **source:** FHIR, openEHR,DAM	
Certainty **T** Coded Text Optional (0..1)	Statement about the degree of clinical certainty that the identified'Specific substance' was the cause of the 'Manifestation' in this reaction event. **source:** FHIR	• **Unlikely** [There is a low level of clinical certainty that the reaction was caused by the identified 'Specific substance'.] • **Likely** [There is a high level of clinical certainty that the reaction was caused by the identified

		'Specific substance'.] • **Confirmed** [There is a very high level of clinical certainty that the reaction was due to the identified 'Substance', which may include clinical evidence by testing or re-challenge.] Possible reasons why null: • unknown
Manifestation T Text Mandatory, repeating (1..*)	Clinical symptoms and/or signs that are observed or associated with the adverse reaction. Comment: Manifestation can be expressed as a single word, phrase or brief description. For example: nausea, rash or no reaction. It is preferable that 'Manifestation' should be coded with a terminology, where possible. The values entered here may be used to display on an application screen as part of a list of adverse reactions, as recommended in the UK NHS CUI guidelines. Terminologies commonly used include, but are not limited to, SNOMED-CT or ICD10. source: FHIR, openEHR,DAM	
Reaction description T Text Optional (0..1)	Narrative description about the adverse reaction as a whole, including details of the manifestation if required. source: FHIR, openEHR	
Onset of the reaction Date/Time Optional (0..1)	Record of the date and/or time of the onset of the reaction. source: openEHR,FHIR, DAM	
Duration of reaction Duration Optional (0..1)	The total amount of time that the manifestation of the adverse reaction persisted. source: openEHR	
Severity of reaction T Coded Text Optional (0..1)	Clinical assessment of the severity of the reaction event as a whole, potentially considering multiple different manifestations. Comment: It is acknowledged that this assessment is very subjective. There may be some some specific practice domains where objective scales have been applied. Objective scales can be included in this model using the 'Reaction details' Cluster in openEHR or extensions in FHIR. source: DAM	• **Mild** [Causes mild physiological effects.] • **Moderate** [Causes moderate physiological effects.] • **Severe** [Causes severe physiological effects.]
Reaction details SLOT (Cluster) Optional, repeating (0..*)	Additional details about the adverse reaction, including anatomical location and Common Toxicity Criteria, can be provided by inclusion of specific archetypes in this SLOT. Comment: For example, photos captured using the Multimedia CLUSTER archetype. [Note: FHIR - These would be extensions as specified in a profile.] source: FHIR, openEHR	**Include:** openEHR-EHR-CLUSTER.anatomical_ location.v1 and specialisations *Or* openEHR-EHR-CLUSTER.multimedia.v1
Initial exposure Date/Time Optional (0..1)	Record of the date and/or time of the first exposure to the Substance for this Reaction Event. Comment: Exposure can be more complicated by more than one exposure events leading to a reaction. Further details about the nature of the exposure can be provided by use of additional archetypes in the 'Exposure details' SLOT or as text in the 'Exposure description'. source: FHIR, openEHR,DAM	
Duration of exposure Duration Optional (0..1)	The total amount of time the individual was exposed to the identified 'Specific substance'. source: openEHR	
Route of exposure T Text Optional (0..1)	Identification of the route by which the subject was exposed to the identified 'Specific substance'. Comment: Coding of the Route of Exposure with a terminology should be used wherever possible. source: FHIR,DAM	

Exposure description **T** Text Optional (0..1)	Narrative description about exposure to the identified 'Specific substance'. **source:** openEHR	
Exposure details SLOT (Cluster) Optional, repeating (0..*)	Additional details about exposure to the 'Specific substance', especially in situations where there may have been multiple or cumulative exposures can be provided by inclusion of specific archetypes in this SLOT. Comment: [Note: FHIR - These would be extensions as specified in a profile.]	**Include:** openEHR-EHR-CLUSTER.citation.v1 and specialisations *Or* openEHR-EHR-CLUSTER.amount.v1
Clinical management description **T** Text Optional (0..1)	Narrative description about the clinical management provided. **source:** openEHR	
Clinical management details SLOT (Cluster) Optional, repeating (0..*)	Additional structured details about clinical management for this reaction event can be provided by inclusion of specific archetypes in this SLOT. Comment: [Note: FHIR - These would be extensions as specified in a profile.]	**Include:** All not explicitly excluded archetypes
Reporting details SLOT (Cluster) Optional, repeating (0..*)	Additional structured details required for reporting to regulatory bodies can be provided by inclusion of specific archetypes in this SLOT. Comment: [Note: FHIR - These would be extensions as specified in a profile.] **source:** FHIR, openEHR	**Include:** All not explicitly excluded archetypes
Information source SLOT (Cluster) Optional, repeating (0..*)	Details about the provenance of the information can be provided by inclusion of specific archetypes in this SLOT. Comment: This SLOT is for FHIR purposes only - the data would be defined in a provenance resource.	**Include:** All not explicitly excluded archetypes
Reaction comment **T** Text Optional (0..1)	Additional narrative about the adverse reaction event not captured in other fields. **source:** openEHR	

PROTOCOL

Structure: Tree Mandatory (1..1) Cardinality: Mandatory, repeating, unordered (*1..*)		
Date recorded Date/Time Optional (0..1)	Date when the propensity/reaction event was recorded or revised. Comment: [Note: FHIR - maps to recordedDate in FHIR.] **source:** openEHR,FHIR.DAM	
Supporting clinical record information URI EHR URI Optional (0..1)	Link to further information about the presentation and findings that exist elsewhere in the health record, including allergy test reports. Comment: For example, presenting symptoms, examination findings, diagnosis etc. [Note: FHIR,DAM: Maps to Sensitivity Test.] **source:** FHIR, openEHR, DAM	
Reporting details Cluster Optional (0..1) Cardinality: Mandatory, repeating, unordered (*1..*)	Additional structured details required for reporting to regulatory bodies can be provided by inclusion of specific archetypes in this SLOT.	
Reaction reported? Boolean Optional (0..1)	Was the adverse reaction reported to a regulatory body? **source:** openEHR	
Report comment **T** Text Optional (0..1)	Additional narrative about the adverse reaction report or reporting process. Comment: For example, the reason for non-reporting. **source:** openEHR	
Adverse reaction report URI URI Optional, repeating (0..*)	Link to an adverse reaction Report sent to a regulatory body. **source:** openEHR	

FHIR record provenance Cluster Optional (0..1) Cardinality: Mandatory, repeating, unordered (*1..**)	FHIR elements that are carried implicitly in the openEHR reference model.	
Subject URIURI Mandatory (1..1)	The patient who has the allergy or intolerance. Comment: openEHR: implicit in the reference model ENTRY/subject. **source:** FHIR	
Identifier IDIdentifier Optional, repeating (0..*)	External Ids for this item. Comment: openEHR: implicit in the reference model ENTRY/id. **source:** FHIR	
Recorder URIURI Optional (0..1)	Indicates who has responsibility for the record. Comment: openEHR: implicit in the reference model ENTRY/provider. **source:** FHIR	