

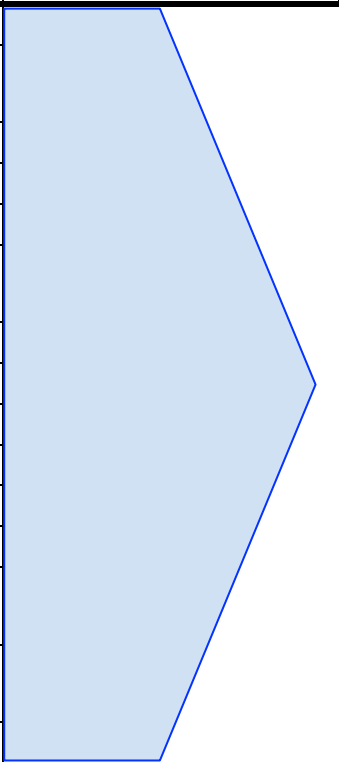
DRAFT International Patient Summary (INTERPAS/IPS)/Data Integrity/Functional Requirements
 HL7 EHR Work Group – Revised 23 October 2016

This DRAFT offers conformance criteria *to support clinical integrity and patient safety and to ensure patient summary (PS) content is “fit for use” at each ultimate point where a trust decision is made.* Thus we start with a basic truth/trust premise:

Truth = factual, authentic = Facts are evident

Trust = assurance, reliance = I am assured, I trust, I rely on (in the first person)

Primary use = clinical care, interventions and decision making; Secondary use = most everything else.

Truth	as evidence for	Trust
✓ Identity is evident		
✓ Actions are evident: e.g., actions taken to support individual health and provide healthcare		
✓ Who took what action when, where and why is evident		
✓ Action facts, findings and observations are evident		
✓ Source, origination and provenance is evident		
✓ Verification and/or attestation (signature) is evident (confirming accuracy/completeness)		
✓ Signature/content binding is evident		
✓ Who authored what when, where and why is evident		
✓ Content is un-altered		
✓ Context is evident		
✓ Completeness (or not) is evident		
✓ Update(s) to original content are evident		
✓ Chain of Trust is evident ✓ From source to use		
✓ Transformation(s) are evident: e.g., to/from exchange artifacts		
✓ Original “Source of Truth” is evident		

International Patient Summary (INTERPAS/IPS)/Data Integrity/Functional Requirements	
The Source/Sending System SHALL/SHOULD/MAY...	The Receiving System SHALL/SHOULD/MAY...
Source	
SHALL render an indication that the PS contains data that is wholly sourced by the sender. [NEW]	SHALL capture, maintain and render an indication that the received PS contains data that is wholly sourced by the sender. [NEW]
SHALL render an indication that the PS contains data that is not wholly sourced by the sender. [NEW]	SHALL capture, maintain and render an indication that the received PS contains data that is not wholly sourced by the sender. [NEW]
Composer/Assembler	
SHALL render an indication that the PS is composed by a human and include: <ul style="list-style-type: none"> • Composer ID • Composer role • Composer digital signature • Composing software/device ID • Composing software/device digital signature • Composing software/device location (network address) • Composed at date/time, time zone • Composed for reason (purpose, intended use) [EHR-S FM RI.1.1.1 + RI.1.1.5, TRUSTED E2E 14.1.2 + 14.5]	SHALL capture, maintain and render an indication that the PS is composed by a human and include related metadata. (← as received from source/sending system) [EHR-S FM RI.1.1.5 + RI.1.1.9, TRUSTED E2E 14.5 + 14.9]
SHALL render an indication that the PS is assembled algorithmically by software or device and include: <ul style="list-style-type: none"> • Assembling software/device ID • Assembling software/device digital signature • Assembling software/device location (network address) • Assembled at date/time, time zone • Assembled for reason (purpose, intended use) [EHR-S FM RI.1.1.1 + RI.1.1.5, TRUSTED E2E 14.1.2 + 14.5]	SHALL capture, maintain and render an indication that the PS is assembled algorithmically by software or device and include related metadata. (← as received from source/sending system) [EHR-S FM RI.1.1.5 + RI.1.1.9, TRUSTED E2E 14.5 + 14.9]
Subject of Care Identification	

International Patient Summary (INTERPAS/IPS)/Data Integrity/Functional Requirements	
The Source/Sending System SHALL/SHOULD/MAY...	The Receiving System SHALL/SHOULD/MAY...
SHALL render PS subject of care (patient, consumer) identifying characteristics and include: <ul style="list-style-type: none"> • Subject name: first middle last • Subject name prefix, suffix and/or title • Subject identifier(s): [listed] • Subject birth gender • Subject birthdate: year month day • Subject address/contact information [EHR-S FM CPS.1.1 + CPS 1.2 + RI.1.1.1, TRUSTED E2E 14.1.2]	SHALL capture, maintain and render PS subject of care identifying characteristics. (← as received from source/sending system) [EHR-S FM CPS.1.1 + CPS.1.2 + RI.1.9.1, TRUSTED E2E 14.1.2]
Authorship and Binding to Content	
SHALL render author of PS data content identifying characteristics and include: <ul style="list-style-type: none"> • Author name: first middle last • Author name prefix, suffix and/or title • Author credential(s) • Author role: source, enterer, observer/witness • Author identifier(s): [listed] • Author address/contact information [EHR-S FM RI.1.1.1 + RI.1.1.2, TRUSTED E2E 14.1.2 + 14.2.2]	SHALL capture, maintain and render author of PS data content identifying characteristics. (← as received from source/sending system) [EHR-S FM RI.1.1.5 + RI.1.1.9, TRUSTED E2E 14.5 + 14.9]
SHALL render the binding of authorship to specific PS data content: <ul style="list-style-type: none"> • At the whole (PS), section or data element level • One to one, one to many [EHR-S FM RI.1.1.1 + RI.1.1.2, TRUSTED E2E 14.1.2 + 14.2.2]	SHALL capture, maintain and render the binding of authorship to specific PS data content. (← as received from source/sending system) [EHR-S FM RI.1.1.5 + RI.1.1.9, TRUSTED E2E 14.5 + 14.9]
Verification/Attestation and Binding to Content	
SHALL render verifier or attester (signer) of PS data content identifying characteristics and include: <ul style="list-style-type: none"> • Verifier/attester name: first middle last • Verifier/attester name prefix, suffix and/or title • Verifier/attester credential(s) • Verifier/attester role: verifier/attester • Verifier/attester identifier(s): [listed] • Verifier/attester address/contact information [EHR-S FM RI.1.1.25, TRUSTED E2E 14.25]	SHALL capture, maintain and render verifier or attester of PS data content identifying characteristics. (← as received from source/sending system) [EHR-S FM RI.1.1.5 + RI.1.1.9, TRUSTED E2E 14.5 + 14.9]

International Patient Summary (INTERPAS/IPS)/Data Integrity/Functional Requirements	
The Source/Sending System SHALL/SHOULD/MAY...	The Receiving System SHALL/SHOULD/MAY...
SHALL render the binding of verification/attestation to specific PS data content: <ul style="list-style-type: none"> • At the whole (PS), section or data element level • One to one, one to many [EHR-S FM RI.1.1.25, TRUSTED E2E 14.25]	SHALL capture, maintain and render the binding of verification/attestation to specific PS data content. (← as received from source/sending system) [EHR-S FM RI.1.1.5 + RI.1.1.9, TRUSTED E2E 14.5 + 14.9]
Provenance and Binding to Content	
SHALL render provenance metadata for PS data content and include: <ul style="list-style-type: none"> • PS subject (patient, consumer) • PS content composer or assembler • PS content author, verifier/attester • PS creation date/time • PS creation location (e.g., network address) • PS creation reason (purpose, intended use) [EHR-S FM RI.1.1.1 + RI.1.1.2 + RI.1.1.8, TRUSTED E2E 14.1.2 + 14.2.2]	SHALL capture, maintain and render provenance metadata for PS data content. (← as received from source/sending system) [EHR-S FM RI.1.1.5 + RI.1.1.9, TRUSTED E2E 14.5 + 14.9]
SHALL render the binding of provenance to specific PS data content: <ul style="list-style-type: none"> • At the whole (PS), section or data element level • One to one, one to many [EHR-S FM RI.1.1.1 + RI.1.1.2 + RI.1.1.8, TRUSTED E2E 14.1.2 + 14.2.2]	SHALL capture, maintain and render the binding of provenance to specific PS data content. (← as received from source/sending system) [EHR-S FM RI.1.1.5 + RI.1.1.9, TRUSTED E2E 14.5 + 14.9]
Context	
SHALL render PS content elements within the context of capture, including full clinical context (e.g., blood pressure = systolic, diastolic, unit of measure, sampling site, sampling method, patient position, patient resting vs. exercise). [EHR-S FM RI.1.1.1 + RI.1.1.6 + RI.1.1.8 + RI.1.2, TRUSTED E2E 14.1.2 + 14.6 + 14.8]	SHALL capture, maintain and render PS content elements within the context of capture, including full clinical context. (← as received from source/sending system) [EHR-S FM RI.1.1.5 + RI.1.1.9 + RI.1.2, TRUSTED E2E 14.5 + 14.9]
Completeness	
SHALL render an indication that PS data content is known to be complete. [EHR-S FM RI.1.1.4 + RI.1.3.1, TRUSTED E2E 14.4]	SHALL capture, maintain and render an indication that the received PS contains data content that is known to be complete. [EHR-S FM RI.1.1.5 + RI.1.1.9 + RI.1.3.1, TRUSTED E2E 14.5 + 14.9]

International Patient Summary (INTERPAS/IPS)/Data Integrity/Functional Requirements	
The Source/Sending System SHALL/SHOULD/MAY...	The Receiving System SHALL/SHOULD/MAY...
SHALL render an indication that PS data content is known to be incomplete. [EHR-S FM RI.1.1.4 + RI.1.3.1, TRUSTED E2E 14.4]	SHALL capture, maintain and render an indication that the received PS contains data content that is known to be incomplete. [EHR-S FM RI.1.1.5 + RI.1.1.9 + RI.1.3.1, TRUSTED E2E 14.5 + 14.9]
Updates	
SHALL render an indication that PS data content is known to have been updated from a prior instance. [EHR-S FM RI.1.1.1 + RI.1.1.2, TRUSTED E2E 14.1.2 + 14.2.2]	SHALL capture, maintain and render an indication that PS data content is known to have been updated from a prior instance. [EHR-S FM RI.1.1.5 + RI.1.1.9, TRUSTED E2E 14.5 + 14.9]
Audit of PS Content Mapping with Transformation, without Transformation, with Mapping Disjunction	
SHALL audit each instance when original data element content is mapped from the source EHR/PHR/other system record entry to the PS data field WITHOUT transformation. [New]	SHALL audit each instance when data element content is mapped from the PS data field to the receiving EHR/PHR/other system record entry WITHOUT transformation. [New]
SHALL audit each instance when original data element content is mapped from the source EHR/PHR/other system record entry to the PS data field WITH transformation. [New]	SHALL audit each instance when data element content is mapped from the PS data field to the receiving EHR/PHR/other system record entry WITH transformation. [New]
SHALL audit each instance when source data element content cannot not be mapped (i.e., source element has no corresponding PS element). [New]	SHALL audit each instance when PS data element content cannot not be mapped (i.e., PS element has no corresponding receiver element). [New]
SHALL render audit reports, summaries and details, to authorized users. [EHR-S FM TI.2.3]	SHALL render audit reports, summaries and details, to authorized users. [EHR-S FM TI.2.3]
IF original data element content is transformed into the form/format required by the PS, THEN the system SHALL render the original unaltered content alongside the transformed content. [EHR-S FM RI.1.1.3]	IF PS data element content is transformed into the form/format required by the receiver, THEN the system SHALL capture, maintain and render the original unaltered content alongside the transformed content. [EHR-S FM RI.1.1.3]

Conformance Criteria (requirements) expressed as per ISO/HL7 10781 EHR System Functional Model Release 2, using these verbs:
 Audit: record the occurrence of an event (e.g., as an entry in an audit log)
 Capture: originate (source), enter (input) or receive data/record content
 Maintain: retain, manage data/record content over time
 Render: create artifact (e.g., for exchange) or display data/record content

Standards References [shown in brackets above]

EHR-S FM = ISO/HL7 10781 Electronic Health Record Functional Model Release 2

TRUSTED E2E = ISO 21089 Trusted End-to-End Information Flows