

# PSS - Regulated Product Submission R2 (Reaffirmation)

[PSS Help and FAQs](#)

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1a. Project Name	Regulated Product Submission R2 (Reaffirmation)
1b. Project ID	1577
1c. Is Your Project an Investigative Project (aka PSS-Lite)?	No
1d. Is your Project Artifact being Reaffirmed or proceeding to Normative directly after being either Informative or STU?	No
1e. Today's Date	
1f. Name of standard being reaffirmed	HL7 Version 3 Standard: Regulated Studies; Regulated Product Submissions (RPS), Release 2
1g. Project Artifact Information	
1h. ISO/IEC Standard to Adopt	
1i. Does the standard include excerpted text from one or more ISO, IEC or ISO/IEC standards, but is not an identical or modified adoption?	
1j. Unit of Measure	
2a. Primary/Sponsor WG	Clinical Decision Support
2d. Project Facilitator	Mark Gray
2e. Other Interested Parties (and roles)	ICH M8 - eCTD Regulatory and Industry Parties
2f. Modeling Facilitator	Marti Velezis
2g. Publishing Facilitator	Marti Velezis
2h. Vocabulary Facilitator	
2i. Domain Expert Representative	Mark Gray
2j. Business Requirements Analyst	Marti Velezis
2k. Conformance Facilitator	
2l. Other Facilitators	

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<b>2m. Implementers</b>	
<b>3a. Project Scope</b>	Reaffirmation Ballot - no changes to standard
<b>Attachments</b>	
<b>3b. Project Need</b>	Reaffirmation of the standard
<b>3c. Security Risk</b>	No
<b>3d. External Drivers</b>	
<b>3e. Objectives/Deliverables and Target Dates</b>	No changes to ballot content. submit for reaffirmation May 2020 Ballot reconciliation at the May WGM and publishing thereafter
<b>3f. Common Names / Keywords / Aliases:</b>	RPS, Regulated Product Submission
<b>3g. Lineage</b>	
<b>3h. Project Dependencies</b>	
<b>3i. HL7-Managed Project Document Repository URL:</b>	<a href="https://confluence.hl7.org/pages/viewpage.action?pageId=66923135">https://confluence.hl7.org/pages/viewpage.action?pageId=66923135</a>
<b>3j. Backwards Compatibility</b>	Yes
<b>3k. Additional Backwards Compatibility Information (if applicable)</b>	
<b>3l. Using Current V3 Data Types?</b>	Yes
<b>3l. Reason for not using current V3 data types?</b>	
<b>3m. External Vocabularies</b>	No
<b>3n. List of Vocabularies</b>	
<b>3o. Earliest prior release and/or version to which the compatibility applies</b>	
<b>4a. Products</b>	V3 Messages - Clinical
<b>4b. For FHIR IGs and FHIR Profiles, what product version(s) will the profiles apply to?</b>	
<b>4c. FHIR Profiles Version</b>	
<b>4d. Please define your New Product Definition</b>	
<b>4d. Please define your New Product Family</b>	
<b>5a. Project Intent</b>	Reaffirmation of a standard
<b>5a. White Paper Type</b>	



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7c. Co-Sponsor 4 Approval Date

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7c. Co-Sponsor 5 Approval Date

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7c. Co-Sponsor 6 Approval Date

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7c. Co-Sponsor 7 Approval Date

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7c. Co-Sponsor 8 Approval Date

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7c. Co-Sponsor 9 Approval Date

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7c. Co-Sponsor 10 Approval Date

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7e. CDA MG Approval Date

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7f. FMG Approval Date

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7g. V2 MG Approval Date

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7h. Architecture Review Board Approval  
Date

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7i. Steering Division Approval Date                      Oct 14, 2019

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7j. TSC Approval Date

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