

SW Development Plan SYDA Project [\[1391\]](#)

1 Project Information and Approval[\[1392\]](#)

Project: SYDA

Development category: New product

Approval Role	DDT Role	Assigne
Document Originator	Software Lead	Srinivasan Duraimani
Ensure appropriateness and completeness given the defined scope.	Software Quality Management	<i>put name here</i>
Ensure content is complete, correct, and aligned with program needs.	Chief Engineer/Technical Lead	<i>put name here</i>
Ensure content is complete and correct.	V&V Engineer	<i>put name here</i>
Add more if required	Add more if required	

2 Introduction[\[1393\]](#)

This SW Development Plan is based in Template <SwDP> PDP-SWL-01.

2.1 Purpose[\[1394\]](#)

The purpose of this document is to establish a medical device Software Development Plan (SwDP) for conducting the activities appropriate to the scope, magnitude, and software safety classification for the project.

Software safety classification shall be used to determine the software lifecycle activities to be applied for software development Note 1.

Note 1 – If the activity is required only for class B or C it will be clearly identified in the section title, otherwise the activity is required for all classes (A, B, C). Enter additional information if applicable.

2.2 Responsibility[\[1395\]](#)

The Software Lead for the project is responsible for this SwDP.

The Software Quality Management for the project is responsible of ensuring that Software Milestone Review being planned and conducted (section of Software Milestone Review Strategy).

Individual software engineers are responsible for adhering to this plan in the development of medical device software.

The intended audiences of this document are the Product Development Team.

This document shall be updated as development proceeds as appropriate.

2.3 Reference Document[\[1396\]](#)

2.4 Glossary and Definitions[\[1397\]](#)

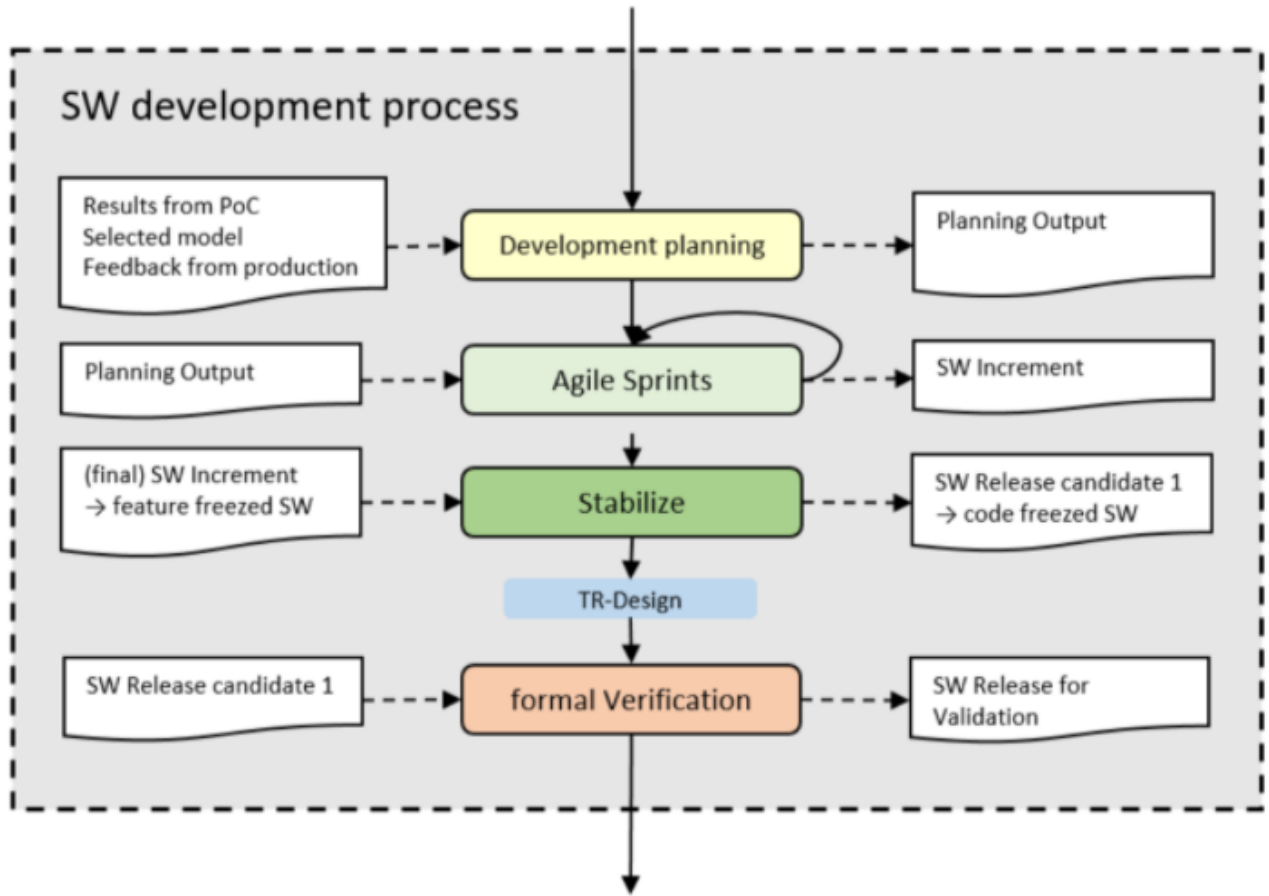
3 Software Development scope and description[\[1398\]](#)

The Software aims to add synthetically generated Abdominal CT scan images to help in balancing Datasets and aid in improving Software Algorithm. The Software is developed to only generate Abdominal CT scans which have No renal stones and is Non contrast. The software can be used by radiologists to generate abdominal CT scans which are similar to realistic data, This data does not contain phi information since these are synthetically generated. Update

4 Software development standards, methods and tools [C][\[1399\]](#)

This Software of Class C is developed using the process defined by our ML cookbook v0.7. check the cook book for more details on the Standards and tools that are used during the development of the software.

5 Software development lifecycle[1400]



The Development lifecycle as defined by our ML cookbook is schematic is shown above. the development is split into 4 sub stages as Planning, Agile sprints, Stabilize and formal verification,

1. Development planning involves preparing documents and ramping up the project team.
2. Agile sprints involve iteratively working on tasks identified by the stake holders and tracking progress on a bi weekly timeline.
3. Stabilize involves feature freeze and getting the software ready for verification also get documents reviewed to be submitted for verification
4. submit all documents and proofs of software.

6 Software risk management planning [\[1401\]](#)

- a) the scope of the planned risk management activities,
 - b) assignment of responsibilities and authorities,
 - c) requirements for review of risk management activities,
 - d) criteria for risk acceptability,
 - e) verification activities, and
 - f) activities related to collection and review of relevant production and post-production information. Include the management of risks relating to SOUP.
- Software safety classification is documented in Software Risk Analysis document.

7 Software integration plan [\[1402\]](#)

Currently no Integration with external platforms/applications are planned.

8 Software configuration management plan[\[1403\]](#)

Project software team and deliverables owners are responsible for performing software configuration management and activities.

All identified configuration items shall be placed under configuration management control before they are verified.

8.1 Software Configuration Management (SCM) Items, Tools and Identification[\[1404\]](#)

All software design history file and software production release (human use release) will be managed in Product Data Management System (PDMS).

SCM Items	SCM Tool	Location in SCM Tool
e.g Source Code	git / Azure Repo	link to Repo
...
...

8.2 Controlled Supporting Items [B,C][\[1405\]](#)

[

The items to be controlled include tools, items or settings, used to develop the software, which could impact the software. Examples of such items include compiler/assembler versions, make files, batch files, and specific environment settings.

]

9 Software deliverables of the activities and tasks[\[1406\]](#)

9.1 Product/Project Level Deliverables[\[1407\]](#)

Group	Document	Author	Reviewers	Approvers	
Data	Data management plan	TL	SQAE, Dev, V&V	SQAL, TL, V&V	
Develop	Plan	SW Development plan	TL	TL, Dev	TL
		SW Maintenance plan	TL	-	-
		SW Verification plan	SQAL	Dev	TL
		Risk management plan	RM	-	-
		HFE evaluation plan	HFE	-	-
	Do	Specification	TL	Dev, TL	TL
		SW Architecture	TL	TL, Dev	TL
		SW detailed design	TL	Dev	TL
		SOUP list	TL	SQAE, CSE	TL, SQAL
	Verify	System test protocol(s)	SQAE	SQAE	TL, SQAL
		Code review records	Dev	SQAE	TL, SQAL
		System test report(s)	SQAE	Dev (Test Eng.)	TL, SQAL
		Unit test report	Dev	Dev (Test Eng.)	TL, SQAL
		SW release notes	TL	Dev, TL	TL, SQAL
		Justified SW anomalies report	TL	Dev	TL
		Trace Report	SQAL	Dev	TL
		Risk management report incl. Safety and Security risk analysis	RM	CSE, TL, PO, CL	-
		HFE evaluation report	HFE	-	-
		IEC 62366-1 report	TL	-	-
	IEC 62304 report	TL	SQAE	TL, SQAL	
IEC 82304-1 report	TL	-	-		

9.2 Software Life Cycle Deliverables[\[1408\]](#)

[

Identify applicable deliverables based on software safety classification and software development scope defined in section 2 of this document. Add additional rows as needed.

The final deliverables (documents number and revision) and justification for non-applicable are listed in the D&DP.

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Deliverables (documents) and their associated milestone:

- Doc1
- Doc2
- Doc3
- ...

10 Software milestones review strategy[1409]

As per our Cook book we have 3 major check points.

CP2: From Development to Validation	<ul style="list-style-type: none">• the prerequisites for start of formal validation are given (previous Technical Review is passed)• the organization is prepared to start formal validation
CP3: From Validation to Deploy	<ul style="list-style-type: none">• Clinical evidence supports the intended use• DHF is finalized (all documents approved)• the organization is ready for commercial launch• the prerequisites for commercial launch are given (previous Technical Review is passed)• Regulatory clearance for first target markets is available <p>→ Ready for release!</p>
CP4: From Deploy to Monitor	<ul style="list-style-type: none">• Software is handed over correctly• Development team can be ramped down <p>→ Service can maintain software!</p>

On top of the checkpoints we have intermediary technical reviews internally to track our progress. these are code reviews which will be tracked in our code review document and Document review which will be tracked using our Review system provide by the Tools.

10.1 Independent Reviewer[1410]

[List independent reviewer(s) here including name and function..

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Independent reviewer(s) will be part of the design review for software development plan, software design input, and software design output. Following individual(s) are identified for this project:

- Reviewer 1 reviews the code base
- Reviewer 2 reviews clinical activities
- Reviewer 3 review Quality assesment and Risk management

10.2 Software Milestone Review Strategy[1411]

[

Describe how many software milestone reviews will be conducted for this project. describe the intend and scope of each software milestone review. If there is a Technical Board Review, identify the relation between software milestone review and technical review.

]

The Software Milestone reviews will be conducted according to the timelines that will be set for each Stage of the Development.

10.3 Software Milestone Review Deviation[\[1412\]](#)

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Describe any deviation against software life cycle process procedure.

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