

Enlisting and Verification of Electronic Health Information Systems

Version 1.0

**Health Information Unit
Ministry of Health**

February 2022

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Acknowledgement:

This document is a product of arduous work carried out by a team of health informaticians listed below. The entire process was supported and supervised by Dr. Champika Wickramasinghe (Deputy Director General, Non-communicable diseases), Dr. S. Sridharan (Deputy Director General, Planning), Dr. Anil Samaranayake (Former Director – Health Information Unit), and Dr. Palitha Karunapema (Director – Health Information).

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Glossary:

Abbreviations

CHI	Consultant Health informatician
DDG	Deputy Director General of Health Services
eHISEC	Electronic Health Information System Evaluation Committee
GoSL	Government of Sri Lanka
HI	Health Information
HIU	Health Information Unit
MO-HI	Medical Officer in Health Informatics
MoH	Ministry of Health
NDHGS	National Digital Health Guidelines & Standards
NeHSC	National eHealth Steering Committee
PDHS	Provincial Director of Health Services
RDHS	Regional Director of Health Services
SLCERT	Sri Lanka Computer Emergency Readiness Team
SW	Software
SyRS	System Requirement Specification

Definitions:

State health sector	Any institute, division or unit in Sri Lanka providing or supporting healthcare and belong to a Ministry, a state department, a provincial department or a local authority. (This does not include healthcare institutes of state-owned companies).
Enlisting	This is the process of listing health information systems that comes under the scope of Enlisting and Verification of the Electronic Health Information Systems, in List-1, 2 or verified list depending on the stage of development of the system considered.
Verified systems	These are the systems that have been added to the Verified list. As those systems have completed the evaluation process, they can be implemented within the state health sector, as agreed.

1. Introduction:

Numerous electronic health information systems are developed and implemented in Sri Lanka, and significant expenditures are associated with such systems. Many of them are expected to improve the efficiency, reliability of the healthcare processes & to meet the expectations of the stakeholders. The emerging information systems address a plethora of different workflows catering to different demands of public and private healthcare institutions.

However, lack of governance mechanisms, the inadequacy of the existing policies has led to limited system integration and interoperability, and duplication of work. There have been efforts in the recent past to rethink and change implementation methodologies in order to streamline and standardize these random implementations.

Therefore, in line with the efforts to develop and implement a Digital Health Blueprint, there is a need to streamline the software applications that are being developed and implemented. As a measure, National Digital Health Guidelines & Standards (NDHGS) are now in effect which will be applicable for electronic Health Information systems in both state & private healthcare sectors.

In addition, the state healthcare sector has now recognized the requirement for a mechanism to enlist the electronic Health Information Systems to maintain a comprehensive list of all available standard software that is used by the health institutions of the state healthcare sector. This effort is expected to assist in planning the value of digital health investments, improve coordination and facilitate the scale up of the systems. All efforts are taken to adhere to global standards including the Digital Health Atlas while developing the tools and methodologies for this enlistment process.

2. Scope:

This is the process of enlisting the electronic Health Information Systems of the state healthcare sector that covers one or more of the following scopes.

- Systems that manage Personally Identifiable Data of healthcare recipients
- Clinical information systems
- Systems managing medical equipment and/ or medical supplies
- Systems handling aggregated data of one or more medical conditions including risk factors & outcomes of the condition(s)
- Implementation research or action research

3. Exclusions:

Systems or databases that are used temporarily for research purposes.

4. Rationale:

The digital health software systems implemented in Sri Lanka are at different levels of maturity. However, the time-tested and mature software can be reused and duplication of efforts to develop

similar software should be minimized to rationalize the investments in Digital Health. Software may represent a specific area of functionality that is used to meet healthcare goals. This initiative will be a stepping-stone to ensure that such software meets the stakeholder requirements and to maintain the standards and interoperability set forth by the Ministry of Health.

5. Expected Outcome:

This initiative will support digital health coordination, documentation, and planning and supports the digital health investments of a country. Also, it is planned to be used as a tool to counteract the country and implementer unfamiliarity with other locally utilized technology that could be adopted and reused. It will serve as a guide to perform evaluations of the implemented digital health for tackling future interoperability challenges in the wider digital health ecosystem. It will ultimately facilitate the government efforts to review the data element and indicators served from the specific digital health software.

6. Process of Enlisting:

Electronic Information Systems that fall within the scope mentioned above need to be enlisted and verified depending on the stage of the software life cycle.

This process of enlistment and verification of electronic Health Information Systems will be executed by the Department of Health Services / Ministry of Health.

The process will have 3 stages. (See Annexure 1)

6.1. Review Stage 1:

Review stage 1 is an optional entry point to the process. This Stage is not mandatory when funds from the Government of Sri Lanka (GoSL) are not utilised.

Preliminary review is done in this stage including the Scope, deliverables and non-functional requirements.

A project proposal shall be forwarded with Form 1 (See Annexure 2). The evaluation body shall enlist the system in List 1 or give its opinions & guidance for resubmission on the proposing system.

6.2. Review Stage 2:

This enlistment process is mandatory for all systems under the purview, including those who got enlisted in List 1.

Electronic Information Systems enlisted in List 1, shall apply to get enlisted in List 2 once coding and β testing processes are completed. This shall be done by submitting Form 2 (See Annexure 3). A system security testing report shall be produced through a reputed third-party organisation, preferably Sri Lanka Computer Emergency Readiness Team (SLCERT).

HIU shall enlist the successful applicants in List 2 or give its opinion & guidance to resubmit the application.

6.3. Review Stage 3:

Electronic Information Systems which are enlisted in List 2, shall apply for verification after completing the piloting of the system by submitting Form 3 (See Annexure 4).

HIU shall recommend the successful applicants for verification status or give its opinion & guidance for resubmission.

Electronic Information Systems that get “verified” status will be endorsed by the National eHealth Steering Committee as and when necessary.

7. Factors considered at each review step:

1. Review stage 1:

- Required documents
 - a.) Form-1
 - b.) Project proposal
- The following will be considered.
 1. Name and version of the solution
 2. Scope of the system
 3. Problem statement and proposed solution
 4. Place of implementation
 5. Licensing category
 6. Ownership
 7. User category
 8. Deliverables
 9. Technical details: Nature of development and software
 10. Funding details

2. Review stage 2:

- Required documents:
 - a.) Form -2
 - b.) Project proposal (if not listed in List-2)
- In addition to the information considered with Form-1, the following will be considered.
 1. Software architecture (document/s)
 2. Database structure (document/s)
 3. Technical and the interoperability standards used (document/s)
 4. System security certificates (document/s)
 5. Details of piloting
 6. Licensing documents
 7. Details of the developer

3. Review stage 3:

- Form 3 shall be forwarded with the software pilot report.

8. Action plan:

8.1. Application process:

Applicants can apply for enlisting in 3 different stages.

For projects funded under GoSL funding; it is mandatory to apply at Review stage 1. (For all other systems, stage-1 is an optional step.) When applying for Review stage 1, the applicant shall submit the duly filled and signed Form-1. A project proposal shall be attached.

Review stage 2 is mandatory for all applicants. To apply, all the applicants shall submit the duly filled and signed Form-2. If the proposing system is not enlisted in list-1, the applicant shall submit a project proposal coupled with Form-2.

All applicants shall apply for the Review stage 3 using Form-3. Form-3 shall be accompanied by a detailed report on the project pilot.

All applications are available online at the ministry website (www.health.gov.lk). The corresponding application/s shall be filled, signed and forwarded to Director (Health Information), with a copy to the Deputy Director General – Planning (DDG-Planning) at the Ministry of Health (MoH) by registered post. It shall be mentioned, “Application for Enlisting a Software” on the upper left-hand side corner of the envelope.

Postal address:

Director health information
Ministry of Health, Nutrition & Indigenous Medicine,
Suwasiripaya,
No. 385,
Rev. Baddegama Wimalawansa Thero Mawatha,
Colombo 10,
Sri Lanka

8.2. Pre-evaluation process:

Once the application is received by registered post, it will be acknowledged by the Director, Health Information Unit at the MoH. Then it will be forwarded to Electronic Health Information System Evaluation Committee (eHISEC) for evaluation.

8.3. Evaluation process:

Evaluation of enlisting and verification of the software is done by Electronic Health Information System Evaluation Committee.

8.3.1. Electronic Health Information System Evaluation Committee

8.3.1.1. Composition:

Evaluation of applications will be done by the Electronic Health Information System Evaluation Committee (eHISEC). The composition of the eHISEC shall be as follows,

Category	Number
Health Administrator	1
Consultant Health informatician	2
Medical Officer – Health Informatics	3
Officers from the Finance department	1
External experts (optional) ICTA / other	1

Table 1 | The composition of eHISEC.

The health administrator may be the Director, Health Information or a health administrator appointed by him/her.

The committee consists of 2 consultant health informaticians (CHI) appointed by Director, Health Information. If the consultants are not available, two other medical officers who are qualified in Health Informatics will be nominated by the Director, Health Information.

Medical officers in Health informatics are selected on a rotation basis from a common pool. All officers in the pool will have equal chances in participating with the committee. MO-HI pool is created by the Director, HI and it may include the officers working at the MoH or any other institution. The basic qualification for getting selected to this pool is having an MSc in Biomedical Informatics awarded by the Post Graduate Institute of Medicine, University of Colombo.

This committee consists of one officer from the financial department of the Ministry of Health. If any other technical opinion is valued depending on the type/scale of the project, external experts shall be appointed.

8.3.1.2. Functionality:

This committee will process the applications for enlisting. Recommendations of the committee shall be forwarded to Director, Health Information. Further, the committee can request clarifications from the applicant where necessary.

The committee will check the applications for the following:

- Stage-1:

The committee will process the stage-1 applications according to the methodology demonstrated in Annexure – 6. If needed any further assessment can be conducted.

Committee decision will be forwarded to Director, Health Information for further action.

- Stage-2:

Applications received for stage-2 will be processed according to the methodology given in Annexure – 7. In addition to the steps shown in the annexure, further evaluations can be carried out.

Committee decision will be forwarded to Director, Health Information for further action.

- Stage-3:

eHISEC will process the application received for the final stage based on the workflow shown in Annexure – 8. Additional investigation can be carried out based on an individual basis.

Decisions will be channelled to Director, Health Information for further actions.

8.4. Post-evaluation process:

Decisions from all 3 evaluation processes will be forwarded to Director, Health Information. These submissions include suggestions for further modifications of the proposed system and final decisions taken at each evaluation stage.

All the suggestions will be forwarded to the applicant through the DDG, Planning. And all the final committee decisions will be forwarded to NeHSC for approval. Those NeHSC approved decisions will be informed to the applicant through the DDG, Planning. Once NeHSC approves, systems proposed for stage-1 evaluation will be enlisted in List-1. And systems applied for stage-2 and stage-3 evaluation will be enlisted in List-2 and Verified list respectively.

8.5. Interim Provisions:

There are Electronic Health Information Systems that fall within the scope of this enlistment process in the State Healthcare sector of Sri Lanka, which are in different stages of their life cycle; (E.g., SyRS, Designing, coding, testing, pilot, implementation, Established or decommissioning phases.)

The systems are eligible to apply for approval using Form 1, 2 or 3 as appropriate. After a specified grace period, any such system that had not been requested for enlisting but found to be existing in a state sector health institution will be advised to be solicited using the appropriate form/s). That software will be dealt with on a case-by-case basis.

8.6. New versions:

Once the Verified status is granted it is free to release new versions intended only for bug fixing. Any new versions of this software need to follow the above procedure beginning with Form 3. The following documents shall be submitted along with the form.

- Proposal
- SyRS (Functional & Non-functional Requirements)
- Ownership
- Licensing
- Software (SW) Architecture
- Database (DB) Structure (including database elements)
- Coding
- Changing scope (Additions/ Omissions)
- User categories

8.7. Remarks:

- Enlisting in List 1, 2 or Verified List under this process shall not be considered as a substitute for ethics review committee approval in case of research.
- Enlisting in List 1, 2 or Verified List under this process shall not be considered as endorsement or assurance of funding through GoSL.

Annexure 1

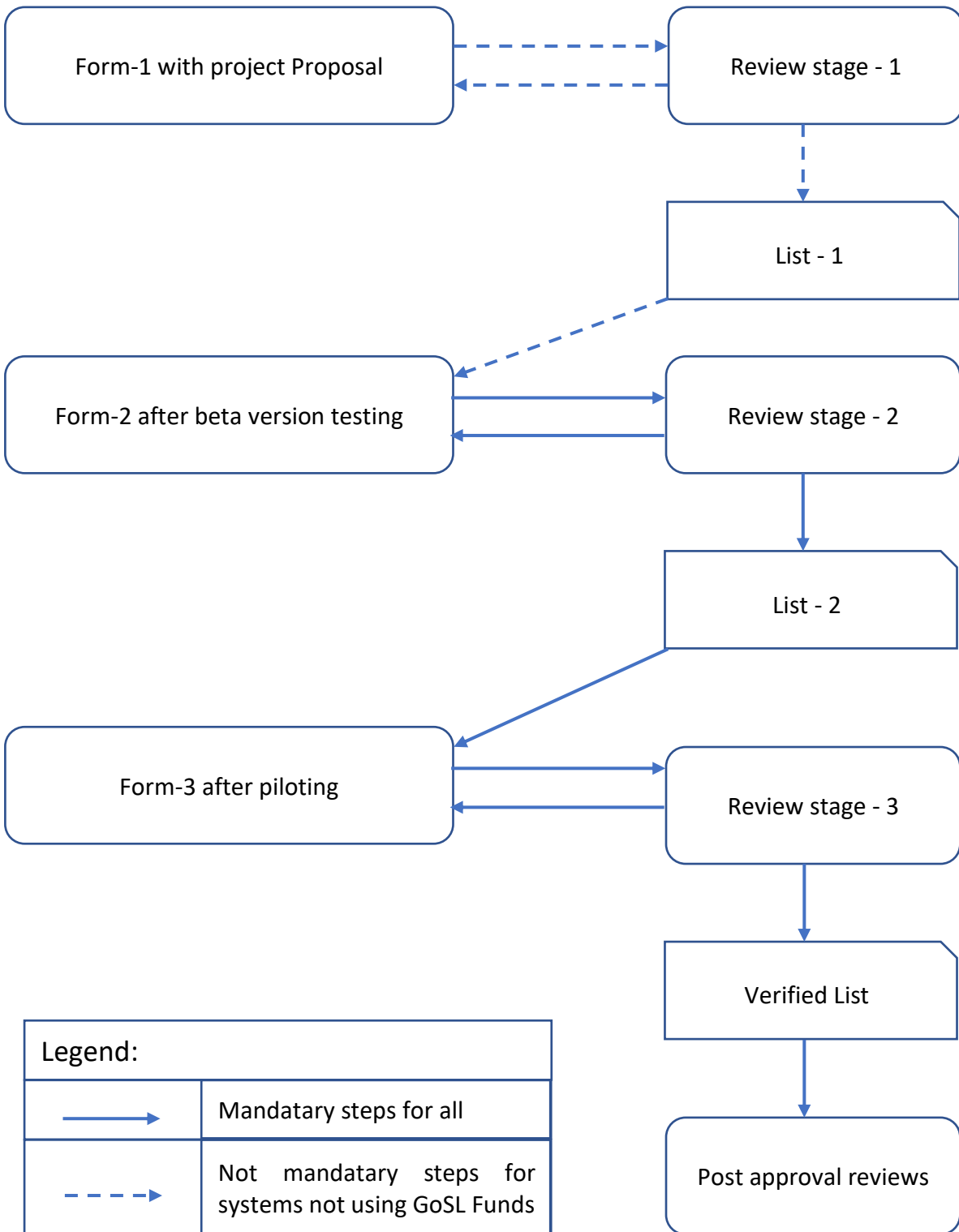


Figure 1 | Enlisting process

Application for Enlistment Electronic Health Information Systems Form – 1 for Enlisting - Stage 1

1. Name of Solution:

2. Version:

3. Main Scope (e.g.: NCD, MCH, Medical Supplies): (Please attach the detailed SyRS)
.....

4. The primary purpose of the solution:

Academic (Research)

Operational

5. Timeline of the project:

5.1. Start date:

5.2. Current stage (Please select):

1. Opportunity and Ideation

2. Preparation and Completion

3. Analysis and Design

4. Implementation Planning

5. Developing or Adopting Solution

6. Piloting and Evidence Generation

7. Package and Advocacy

8. Deploying

9. Scaling Up

10. Handover or Complete

6. Summary of the proposal:

6.1. What are the Health System Challenges addressed by the Digital Health Intervention?

6.2. Proposed Solution:

7. If existing solutions are available for the same scope, rationale of the proposed solution:
(Attach separate sheets if needed)

8. Places (category) of Implementation:

9. Copyright details:

9.1. Licensing Type* (Please attach the licensing document):

- | | | | |
|---------------|--------------------------|--|--------------------------|
| No Licensing | <input type="checkbox"/> | Non-protective Free and Open Source Software | <input type="checkbox"/> |
| Commercial | <input type="checkbox"/> | Protective Free and Open Source Software | <input type="checkbox"/> |
| Freemium | <input type="checkbox"/> | Owned by an entity of GoSL | <input type="checkbox"/> |
| Public Domain | <input type="checkbox"/> | | |

9.2. Ownership [Person(s) / Organisation(s)]:

9.3. Owners category:

- | | | | |
|------------------------|--------------------------|--|--------------------------|
| Ministry of Health | <input type="checkbox"/> | Provincial Department of Health Services | <input type="checkbox"/> |
| Local government | <input type="checkbox"/> | Private Organisation | <input type="checkbox"/> |
| NGO | <input type="checkbox"/> | | |
| Other (Please Specify) | <input type="checkbox"/> | | |

10. Front user category of the proposing system:

- | | |
|---|--------------------------|
| Medical Administrators | <input type="checkbox"/> |
| Clinicians | <input type="checkbox"/> |
| Nurses | <input type="checkbox"/> |
| Paramedical professions supplementary to medicine | <input type="checkbox"/> |
| Other (Please Specify): | |

11. Deliverables: (Can select more than one)

- | | | | |
|----------------------------------|--------------------------|---------------------|--------------------------|
| Executable software | <input type="checkbox"/> | Licences | <input type="checkbox"/> |
| User Manual (for front end uses) | <input type="checkbox"/> | Development Guide | <input type="checkbox"/> |
| Technical Manual | <input type="checkbox"/> | Sustainability Plan | <input type="checkbox"/> |
| Source code | <input type="checkbox"/> | | |

11.1. Please provide a link to code documentation (optional):

.....

11.2. Please provide a link to a demo of the solution (Optional):

.....

11.3. Please provide a link to the solution wiki page (Optional):

.....

12. Technical Details

12.1. Nature of the development:

- Bespoke
- Off the shelf
- Customised

12.2. Nature of the software:

- Stand-alone
- Web-based
- Predominantly Mobile-based
- Mixed

13. Funding details:

13.1. Funding source: (Can select more than one)

- | | | | |
|-------------------|--------------------------|---------|--------------------------|
| GoSL | <input type="checkbox"/> | UN body | <input type="checkbox"/> |
| Private institute | <input type="checkbox"/> | Other | <input type="checkbox"/> |

13.2. Approximate cost of development:

14. Conflicts of interests:

15. Signatures of the applicant/ applicants:

I/we/The company hereby attest that all details provided above are true to my/our/company's knowledge.

I understand that the Ministry of Health reserves the right, in its sole discretion, to decide on applications for enlisting and/ or verification of electronic health information systems and the Ministry of Health shall not be liable for any loss whatsoever to me/us/the company by reason of any such decision made.

Similarly, if my/our/company's conduct violates any policies, regulations or procedures of the Ministry of Health, I/we/the company understand that enlisting status and/ or the verification status of the concerned health information system may be withdrawn, at the sole discretion of the Ministry.

.....
Signature of the Applicant(s)

Name of the Applicant :
Contact Number :
Contact email :
Designation :
Date :

Recommended and forwarded.

.....
Head of the institution, head of decentralized unit/ special campaign

Name :
Designation :
Date :

Application for Enlistment Electronic Health Information Systems

Form-2 for Enlisting - Stage 2

*** If included in the Listing - 1, shall fill 7.4, 12.3, 12.4, 12.5, 12.6, 15 and 16 below unless the system was changed beyond what was stated in Form-1. Others shall fill out the complete form. In addition, all licensing documents shall be attached.

List 1 Number (if applicable):

1. Name of Solution:

2. Version:

3. Main Scope (e.g.: NCD, MCH, Medical Supplies): (Please attach the detailed SyRS)

.....

4. The primary purpose of the solution:

Academic (Research)

Operational

5. Timeline of the project:

5.1. Start date:

5.2. Current stage (Please select):

1. Opportunity and Ideation

6. Piloting and Evidence Generation

2. Preparation and Completion

7. Package and Advocacy

3. Analysis and Design

8. Deploying

4. Implementation Planning

9. Scaling Up

5. Developing or Adopting Solution

10. Handover or Complete

6. Summary of the proposal:

6.1 What are the Health System Challenges addressed by the Digital Health Intervention?

6.2 Proposed Solution:

7. If existing solutions are available for the same scope, rationale of the proposed solution:
(Attach separate sheets if needed)

8. Places (category) of Implementation:

9. Copyright details:

9.1. Licensing Type* (Please attach the licensing document):

- | | | | |
|---------------|--------------------------|--|--------------------------|
| No Licensing | <input type="checkbox"/> | Non-protective Free and Open Source Software | <input type="checkbox"/> |
| Commercial | <input type="checkbox"/> | Protective Free and Open Source Software | <input type="checkbox"/> |
| Freemium | <input type="checkbox"/> | Owned by an entity of GoSL | <input type="checkbox"/> |
| Public Domain | <input type="checkbox"/> | | |

9.2. Ownership [Person(s) / Organisation(s)]:

9.3. Owners category:

- | | | | |
|------------------------|--------------------------|--|--------------------------|
| Ministry of Health | <input type="checkbox"/> | Provincial Department of Health Services | <input type="checkbox"/> |
| Local government | <input type="checkbox"/> | Private Organisation | <input type="checkbox"/> |
| NGO | <input type="checkbox"/> | | |
| Other (Please Specify) | <input type="checkbox"/> | | |

9.4. Details of the developer:

- 9.4.1. Name :
- 9.4.2. Address:
- 9.4.3. Phone :
- 9.4.4. Fax :
- 9.4.5. Email :

9.5. Please enlist the names/emails of the Team Members:

	Name	E-mail
Principal contact (Mandatory)	_____	_____
Other team members (Optional)	_____	_____
	_____	_____
	_____	_____
	_____	_____

10. Front user category of the proposing system:

- Medical Administrators
- Clinicians
- Nurses
- Paramedical professions supplementary to medicine
- Other (Please Specify):

11. Deliverables: (Can select more than one)

- | | | | |
|----------------------------------|--------------------------|---------------------|--------------------------|
| Executable software | <input type="checkbox"/> | Licences | <input type="checkbox"/> |
| User Manual (for front end uses) | <input type="checkbox"/> | Development Guide | <input type="checkbox"/> |
| Technical Manual | <input type="checkbox"/> | Sustainability Plan | <input type="checkbox"/> |
| Source code | <input type="checkbox"/> | | |

11.1. Please provide a link to code documentation (optional):

.....

11.2. Please provide a link to a demo of the solution (Optional):

.....

11.3. Please provide a link to the solution wiki page (Optional):

.....

12. Technical details:

12.1. Nature of the development:

- Bespoke
- Off the shelf
- Customised

12.2. Nature of the software:

- Stand-alone
- Web-based
- Predominantly Mobile-based
- Mixed

12.3. Software architecture: (Please attach the document).

12.4. Database structure: (Please attach the document).

12.5. Technical and the interoperability standards used: (Please attach the document).

12.6. System security certificates: (Please attach the document).

13. Funding details:

13.1. Funding source: (Can select more than one)

- GoSL UN body
- Private institute Other

13.2. Approximate cost of development:

14. Conflicts of interests:

15. Details of piloting:

- 15.1. Duration:
- 15.2. Place/s:

16. Signatures of the developer and the applicant:

16.1. Developer:

I hereby attest that all details provided above are true to my knowledge.

.....
Signature of the Developer

Designation:

Date :

16.2. Applicant(s):

I/we/The company hereby attest that all details provided above are true to my/our/company's knowledge.

I understand that the Ministry of Health reserves the right, in its sole discretion, to decide on applications for enlisting and/ or verification of electronic health information systems and the Ministry of Health shall not be liable for any loss whatsoever to me/us/the company by reason of any such decision made.

Similarly, if my/our/company's conduct violates any policies, regulations or procedures of the Ministry of Health, I/we/the company understand that enlisting status and/ or the verification status of the concerned health information system may be withdrawn, at the sole discretion of the Ministry.

.....
Signature of the Applicant(s)

Name of the Applicant :

Contact Number :

Contact email :

Designation :

Date :

Recommended and forwarded.

.....
Head of the institution, head of decentralized unit/ special campaign

Name :

Designation :

Date :

Application for Enlistment Electronic Health Information Systems Form-3 for Enlisting - Stage 3

*** If the system has changed after the enlistment at List-2, this form shall be attached with a fresh Form-2.

List 2 Number:

1. Name of Solution:

2. Version:

3. Main Scope (e.g.: NCD, MCH, Medical Supplies): (Please attach the detailed SyRS)

.....

4. Has the system changed from the specifications given with Form-2 during the enlistment process? (If the answer is “Yes”, Please attach a new Form-2.)

Yes No

5. Details of piloting:

5.1. Duration:

5.2. Place/s:

5.3. Outcome: (Please attach a detailed report)

6. Geographic Scope of the project

National

Sub National

6.1 If Sub-national; please list the Provinces/RDHS/MOH/Institutions where the solution is to be implemented. (Please attach a detailed list if applicable)

.....

6.2.How many health workers will use the system? (Please provide an approximate value)

- | | | | |
|----------|--------------------------|------------|--------------------------|
| 1-10 | <input type="checkbox"/> | 10-100 | <input type="checkbox"/> |
| 100-1000 | <input type="checkbox"/> | 1000-10000 | <input type="checkbox"/> |
| >10000 | <input type="checkbox"/> | | |

6.3.How many clients will use the system? (Please provide an approximate value)

6.3.1. Current users (at the date of submission of the form):

6.3.2. Users after full implementation:

7. Signatures of the developer and the applicant:

7.1.Developer:

I hereby attest that all details provided above are true to my knowledge.

.....

Signature of the Developer

Designation:

Date :

7.2.Applicant(s):

I/we/The company hereby attest that all details provided above are true to my/our/company's knowledge.

I understand that the Ministry of Health reserves the right, in its sole discretion, to decide on applications for enlisting and/ or verification of electronic health information systems and the Ministry of Health shall not be liable for any loss whatsoever to me/us/the company by reason of any such decision made.

Similarly, if my/our/company's conduct violates any policies, regulations or procedures of the Ministry of Health, I/we/the company understand that enlisting status and/ or the verification status of the concerned health information system may be withdrawn, at the sole discretion of the Ministry.

.....
Signature of the Applicant(s)

Name of the Applicant :
Contact Number :
Contact email :
Designation :
Date :

Recommended and forwarded.

.....
Head of the institution, head of decentralized unit/ special campaign

Name :
Designation :
Date :

Annexure 5

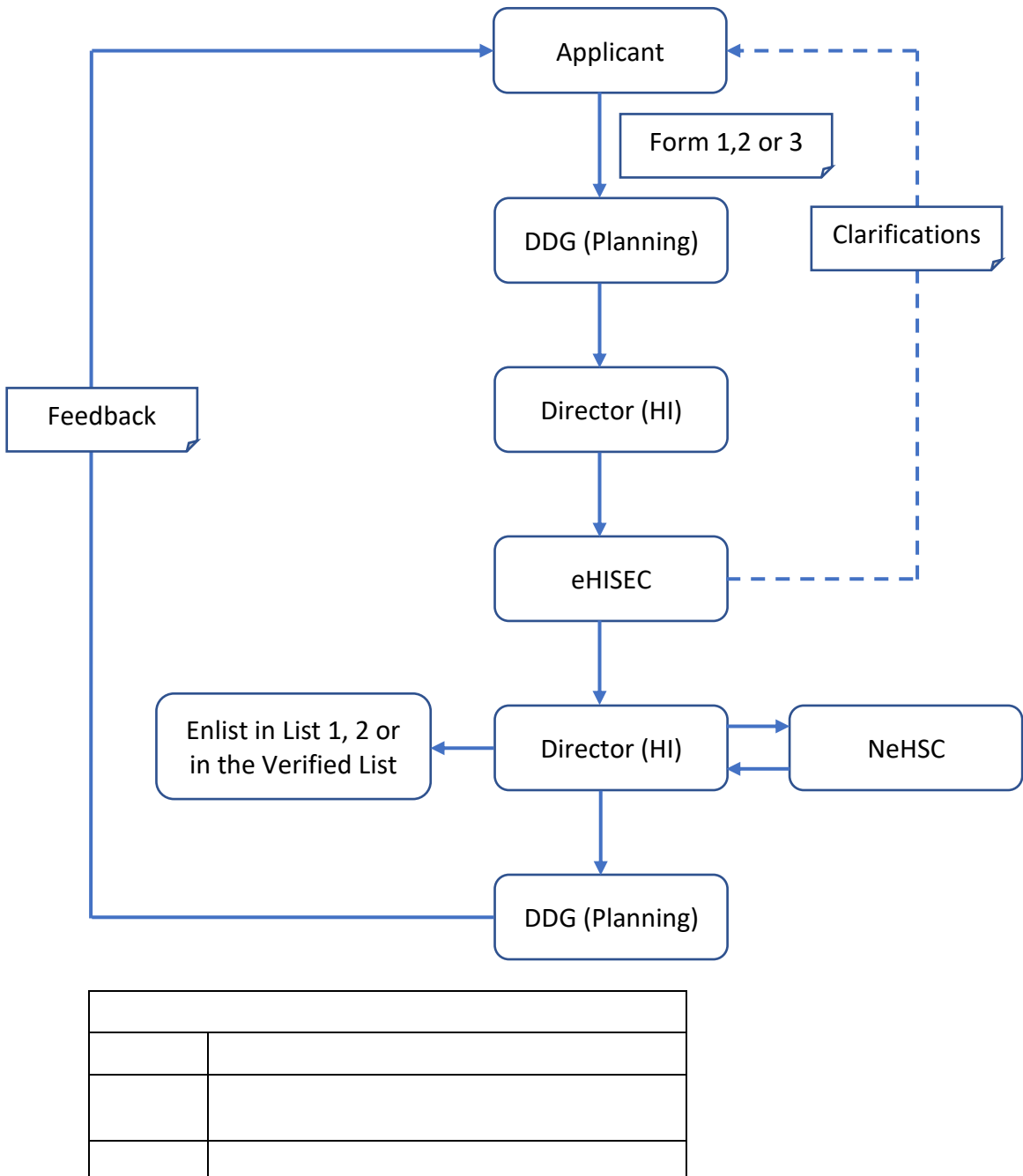
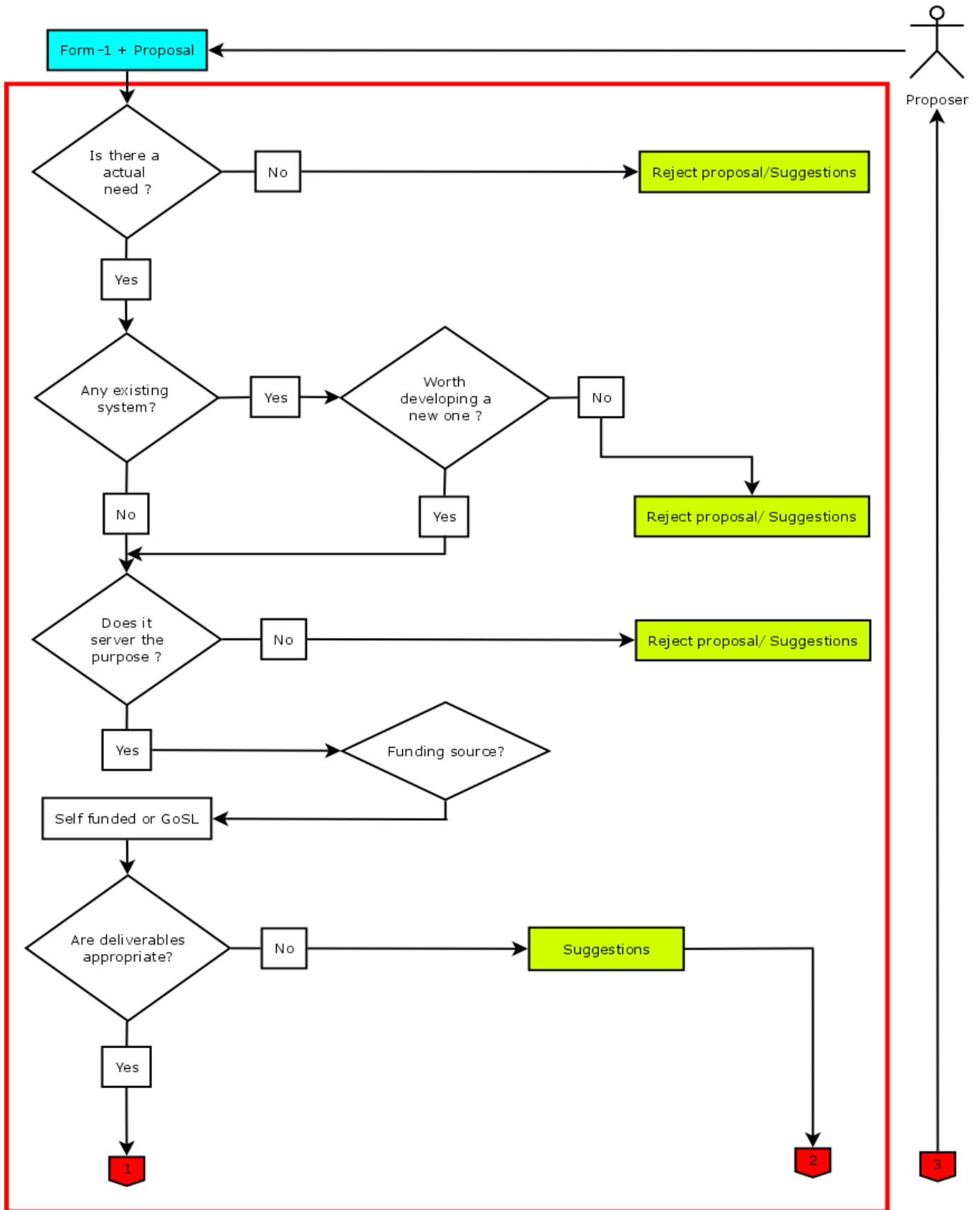
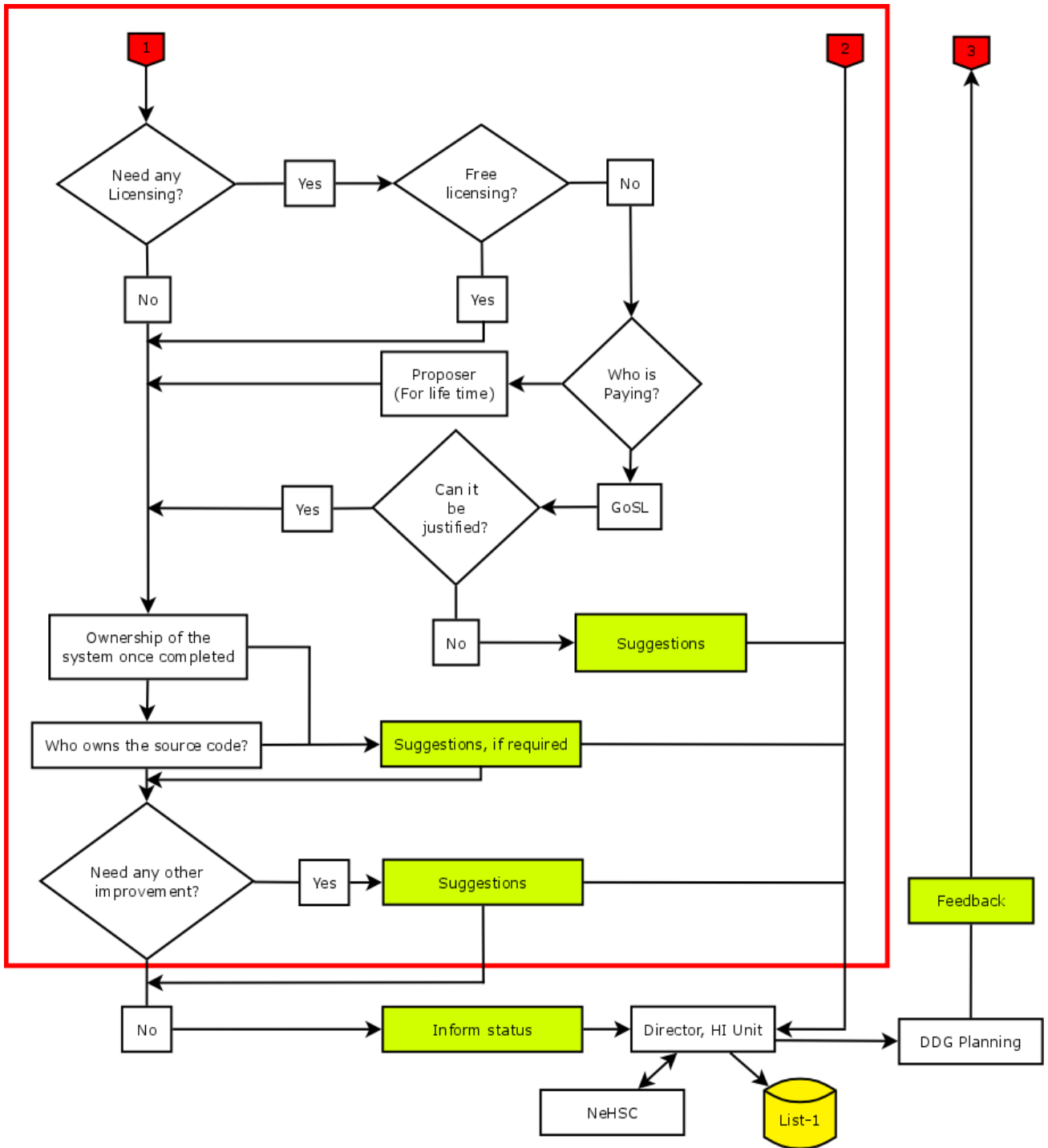


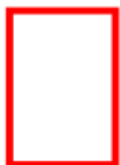
Figure 2 | Overview of the action plan

Annexure 6





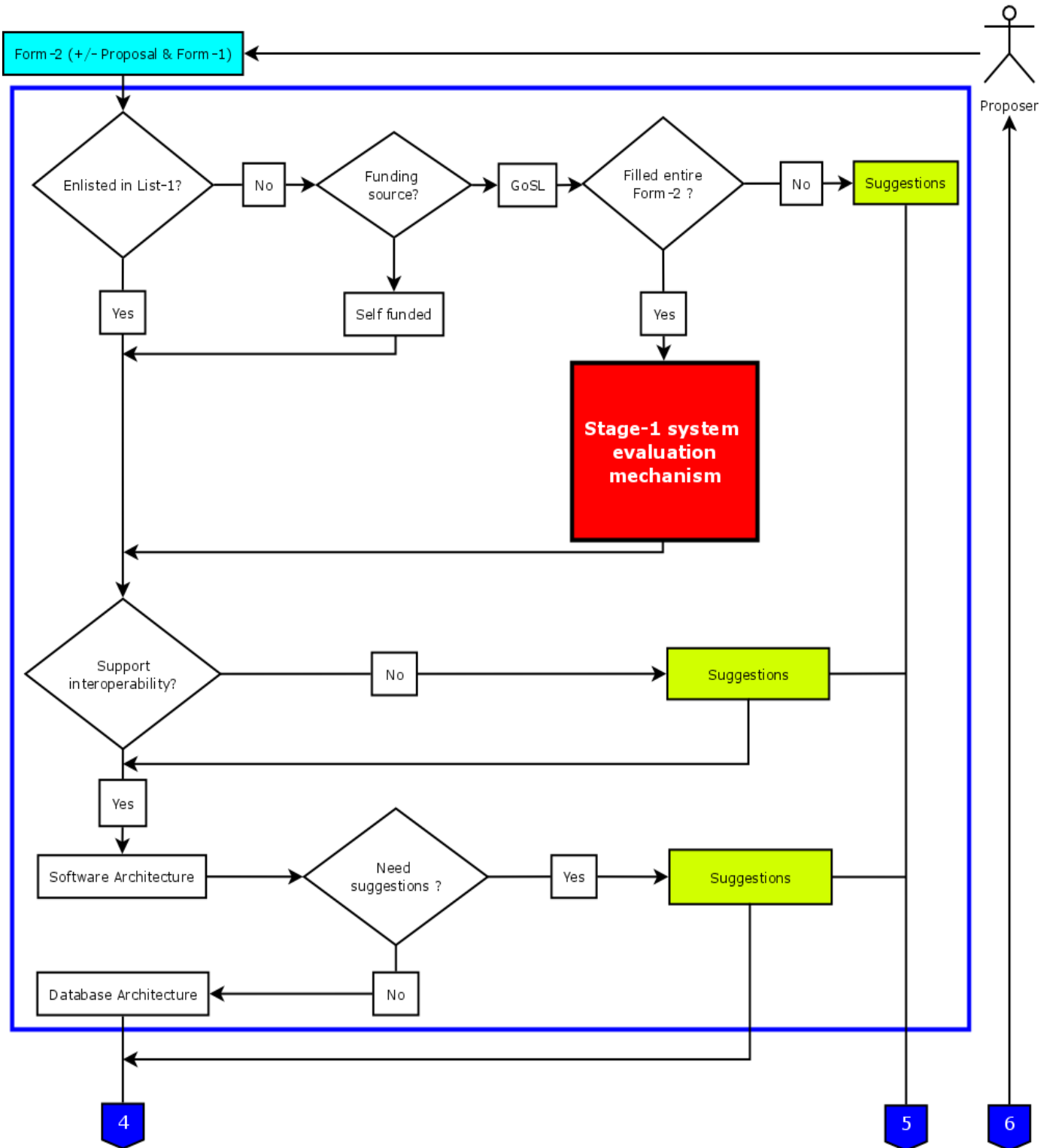
Legend



= Stage-1 system evaluation mechanism

Figure 3 | Stage-1 of software evaluation mechanism

Annexure 7



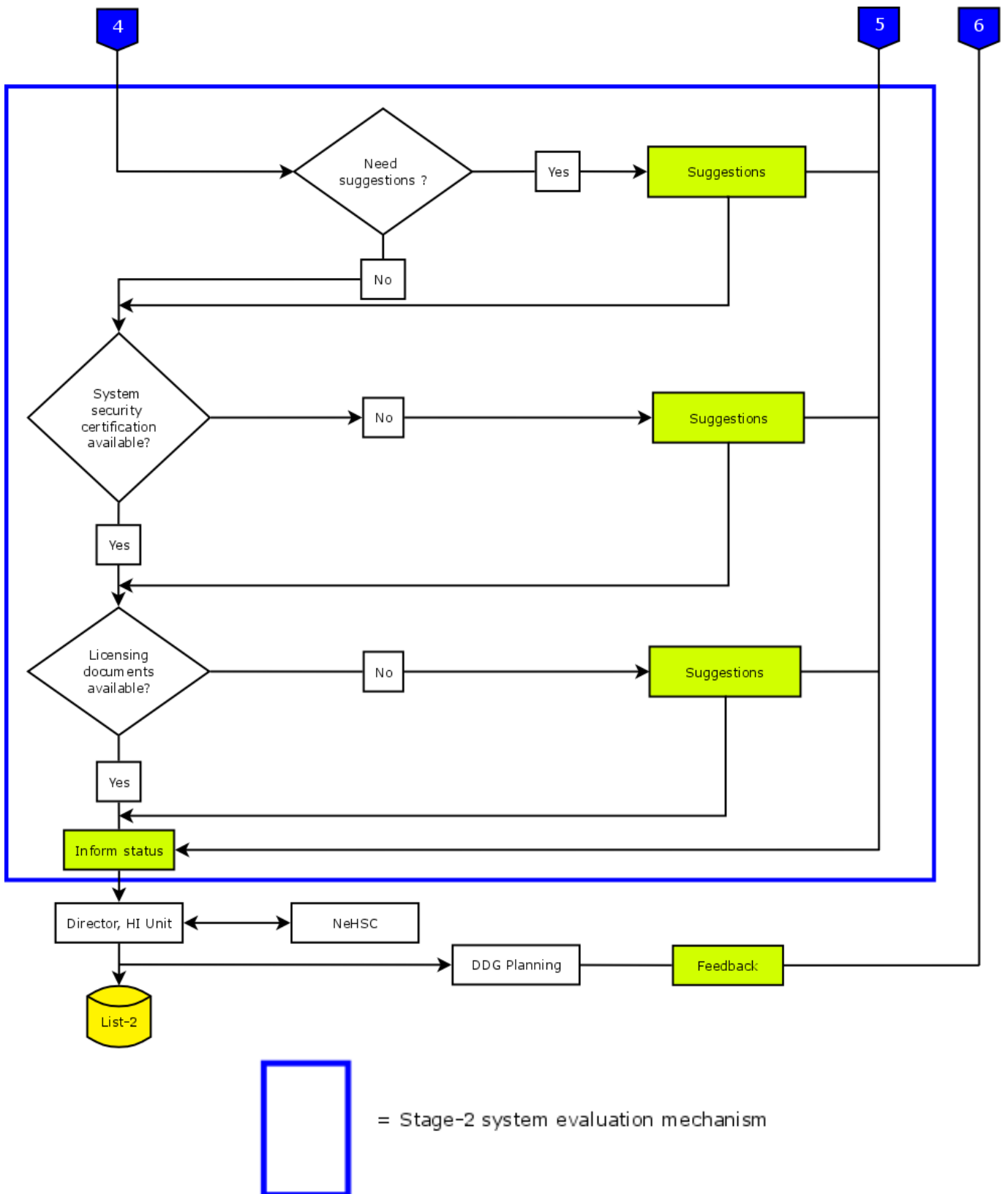


Figure 4 | Stage -2 software evaluation mechanism

Annexure 8

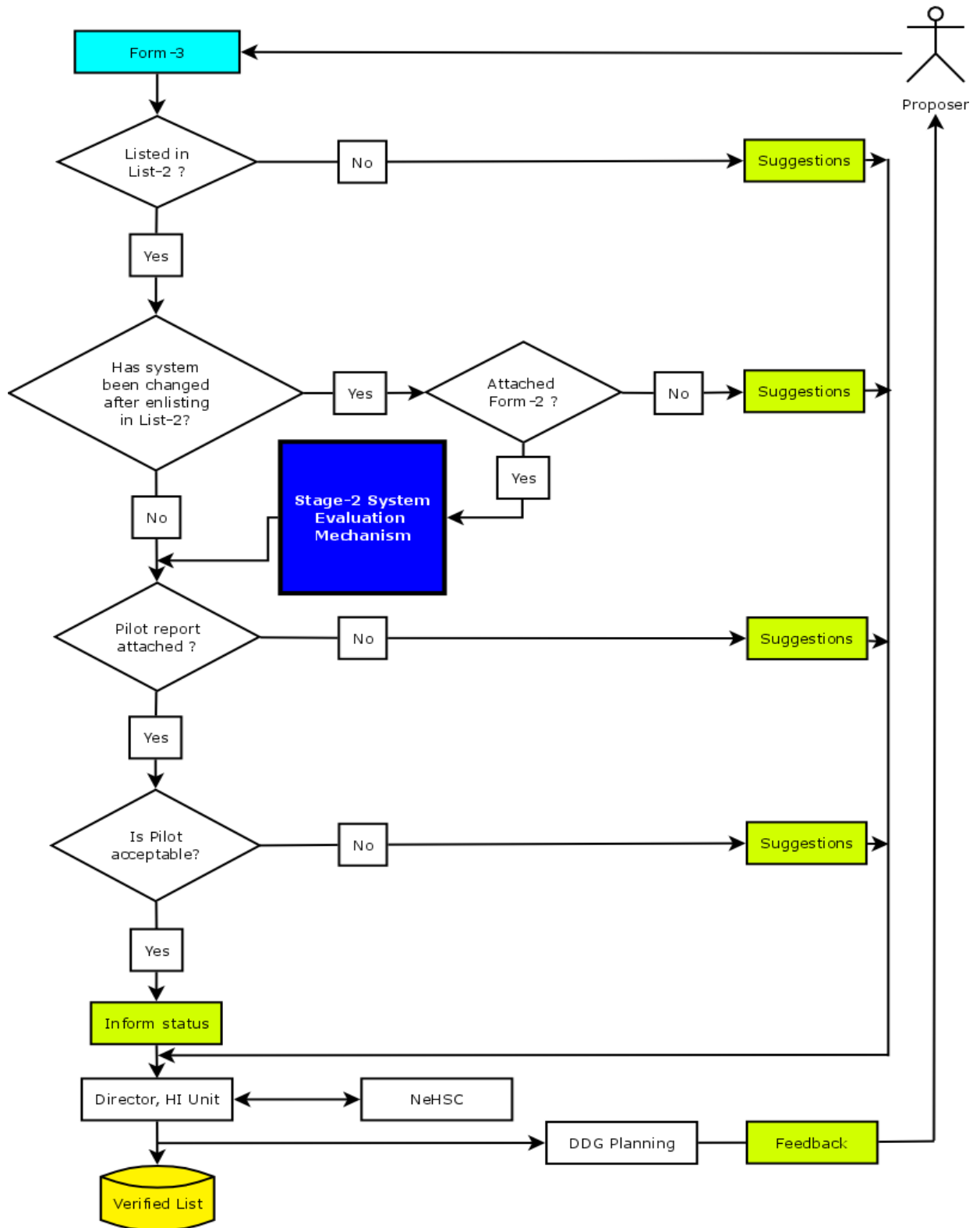


Figure 5 | Stage 3 software evaluation mechanism

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