



GS1 Project of INNOVAX

Linda
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Contents

01		Background	06		Consultancy
02		Objectives	07		General Costs & Regulatory actions
03		Project organization	08		Outcomes
04		Main actions of the project	09		Challenges
05		Components required for implementing the project	10		Experiences & Conclusion

1 Background

Assessing the Programmatic Suitability of Vaccine Candidates for WHO Prequalification (rev. 2014), preferred characteristics:

- Bar codes are recommended on all packaging levels used by manufacturers, **with the exception of primary packaging**, and should conform to GS1 standards and associated specifications.
- Bar code data should include the Global Trade Item Number (GTIN), lot number, and expiry date.



GAVI announcement: vaccine manufacturer GS1 compliance

*GS1 barcoding on the **secondary packaging** will be a requirement by latest 31st December 2021 for vaccine tenders backed by Gavi financing and issued by UNICEF.*

News note

UNICEF



6 November 2020 – CONFIDENTIAL

DCVMN OPEN CALL FOR EXPRESSION OF INTEREST IN JOINING A CONSORTIUM PURSUING A TRACEABILITY PILOT PROJECT: **IMPLEMENTING BARCODING ON PRIMARY PACKAGING OF VACCINES** USING A QUALITY BY DESIGN PROCESS

GUIDANCE FOR APPLICANTS

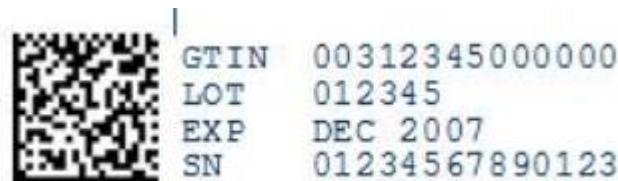
DCVMN International periodically sponsors technical assistance to member companies by internationally-reputable expert consultants and/or services, to improve manufacturing technology, processes or quality control systems. The objective is to increase the availability of high-quality vaccines globally.

2 Objective

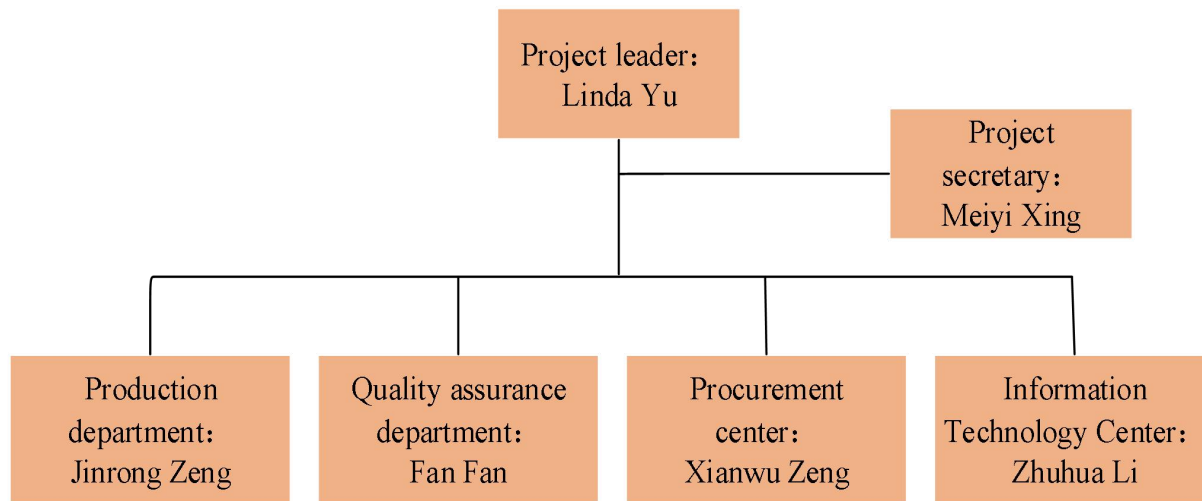
To complete implementation of barcoding on secondary packaging using standard GS1 barcodes for HPV16/18 bivalent vaccine before end of 2021. The barcoding for secondary package will contain **GTIN, lot number, and expiry date**.

The pilot will focus on: **secondary packaging**

eg:

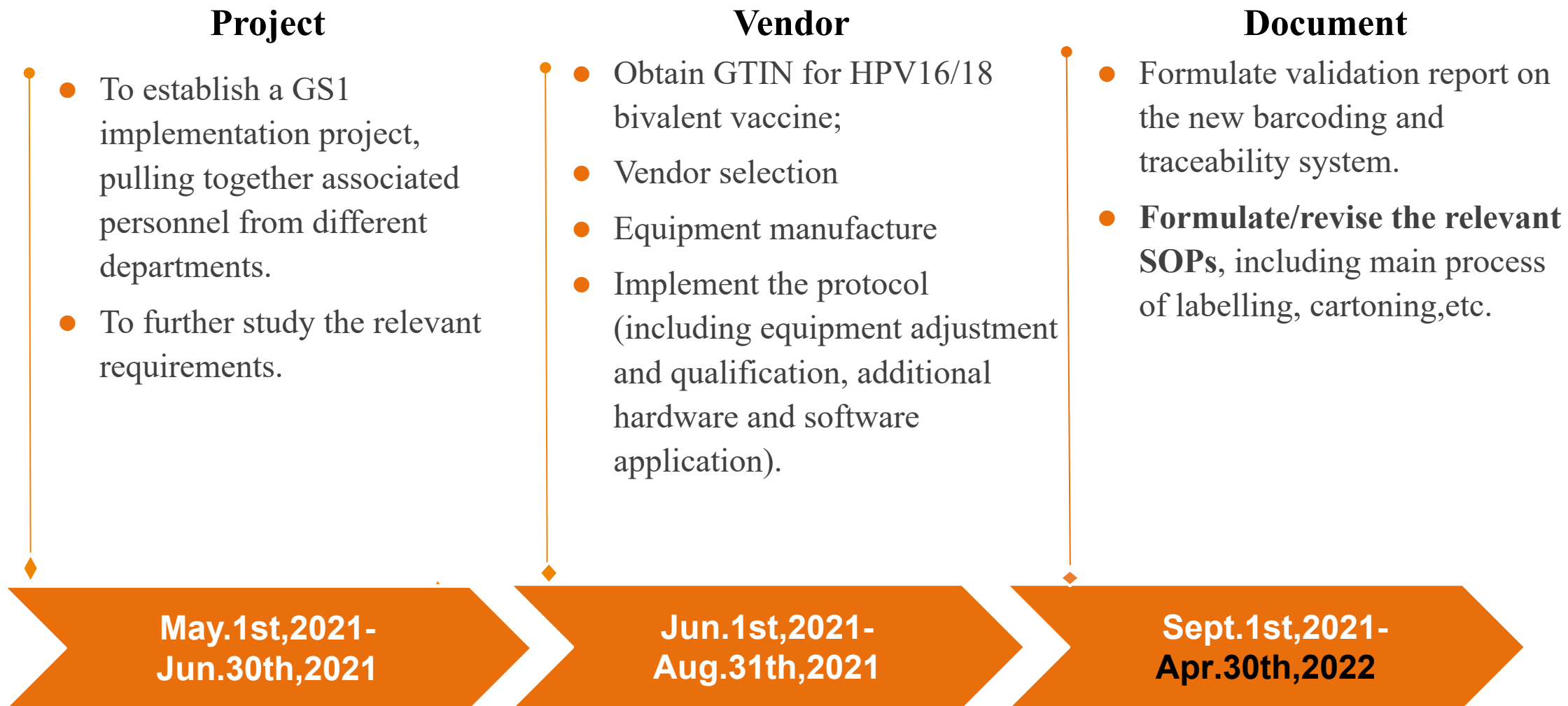


3 Project organization



Role	Responsibilities	staffs
Project leader	Responsible for the overall project promotion, project planning, staffing planning, etcResponsible for the coordination of the relationship between functional departments involved in the projectResponsible for regular report on the project progress;Responsible for the management of project team members	Linda Yu
Project secretary	Assist the project manager in project management ; Responsible for project progress tracking and coordinationResponsible for organizing regular project management meetingsResponsible for archiving project management data	Meiyi Xing
Team member	Participate in protocol design, assist vendor to adjust and validate the system	Jinrong Zeng
Team member	Responsible for GTIN code application and GS1 traceability code supplier assessment	Fan Fan
Team member	Responsible for procurement of GS1 tracking code related equipment	Xianwu Zeng
Team member	Assist GS1 tracking code related software to connect with company information system	Zhuhua Li

4 Main actions of the project



5 Components required for implementing the project

Hardware

- | | |
|---|--|
| 1 | Code assignment industrial control machine |
| 2 | Coding conveying machine |
| 3 | Inkjet printer |
| 4 | Scanning devices |
| 5 | Label printer |
| 6 | Hand scanner |
| 7 | Intelligence terminal devices |
| 8 | Supporting materials |

Software

- | | |
|---|--------------------------------------|
| 1 | PDM system |
| 2 | Code assignment system |
| 3 | Industrial computer operating system |
| 4 | Server operating system |
| 5 | Database software |

Servers and public devices

- | | |
|---|------------------------|
| 1 | Code assignment server |
|---|------------------------|



6

Consultation company: Beijing Accture Technology Co., Ltd.

● GS1 Standard Training

Two training were held by Accture on June and July.

Focus on :

- GS1 introduction
- GS1 implementation flow
- How to apply GS1 barcode
- GS1 barcoding system
- Barcoding principles and methods

● GS1 barcoding system and equipment operation

- ESC coding system and related operation training (template printing, coding rules, etc.)
- Operation of layer scanning camera
- Camera operation of detecting secondary package and tertiary package
- Coding process and handling of abnormal situation.

文件编号：HR-03-001-R01

Doc Code:

版本号：1.0

Rev:

实施日期：2021.06.01

Implementation Date: Jun.01.2021

培训签到记录表
Training Attendance Record Form

TRA_O_20170112

2017-01-12

培训日期 Date		培训课程 Training Course	
2021.06.18		(GSI) 标准实验室	
培训时间 Time			
18:00 - 18:30			
培训地点 Location		培训方式 Training Method	
(C12)		<input checked="" type="checkbox"/> 课堂培训 classroom training <input type="checkbox"/> 自学培训 self-learning training <input type="checkbox"/> 一对一培训 one-on-one training <input type="checkbox"/> 岗位操作培训 OJT	
		应到人数 Required Attendance	实到人数 Actual Attendance
		13	13
部门/Department	工号/Employee ID	姓名/Print Name	
1 国际销售部	214502	蒋佳迪	
2 国际销售部	20700	叶芳青	
3 物流部	20537	叶芳青	
4 质量部	21406	林健明	
5 质量部	20609	蔡敏 2021.06.18	
6 质检部	21016	陈生妹	
7 法规部	20789	肖引华	
8 设备工程部	20973	戴伟强	
9 设备工程部	21690	肖引华	
10 设备工程部	21100	肖引华	
11 生产部	20141	林健明	
12 生产部	20339	周礼标	
13 设备工程部	20977	林健明	

评估方式 Evaluation method:

☐ 培训试卷 Training test paper ☐ 课堂问答 Class Q&A ☐ 操作技能评估 Operational skills evaluation

☐ 自学、已阅读并理解培训内容 Self-learning training, have read and understood the training content

☐ 其它评估方式，请注明 Other evaluation method, please indicate.

培训师签名/日期（外来讲师请填写其公司）

Trained by Date (If training is provided by external trainer, indicate trainer's company): 刘杰 (客训) (代)

Operational skills evaluation
of the training content

229166

27502

Traning records

7 General Costs & Regulatory actions

General costs: about 200,000 USD

Regulatory actions: Change control procedure including the actions and timelines

8 Outcomes

- **Vendor selection**

After survey on different vendors on this domain, we finally selected Beijing Accture Technology Co., Ltd. as our vendor to conduct GS1 barcoding. URS were also submitted to the vendor.

- **Successfully obtain GTIN**

The GTIN for our bivalent HPV product is 6957602700009(Attachment 2)

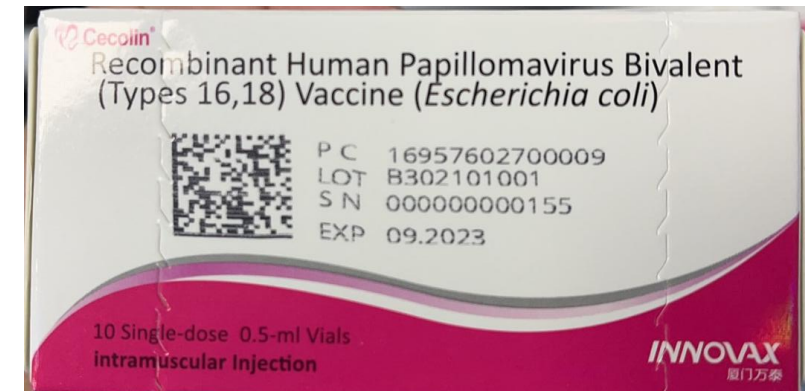
- **Successfully completed the validation of the equipment**

We have successfully completed the FAT, installation and adjustment, as well as qualification of the newly added barcoding equipment. And also, we have completed the design of the secondary packaging.

- **Completed drafting the important relevant SOP**

A.SOP for GS1-barcoding system management

B.SOP for Packaging of export products(including Batch records for Packaging of export products)



9 Challenges

- Lack of experience for barcoding according to GS1 specification leading to much more difficulties to implementation. To deal with this, the consultation from Acctrue help us a lot.
- Influenced by the global COVID-19 epidemic, the project progress had been postponed for twice, which leading to the change of the project. To deal with this, we communicated with relevant department in time and make the solution, such as: during the qualification of the equipment, the engineer of the vendor can not come to the site due to the COVID-19 epidemic, instead, we carried out the on-line guiding which prevent the project from postponing for too long time.

10 Experience & Conclusion

Experience:

- Keep close contact with the vendor
- Keep close contact with the other departments
- Need to train internal personnel to better master the equipment operation principle, in order to deal with the emergency situation.

Conclusion:

The whole preparation for GS1-barcoding of our bivalent HPV vaccine for the UN market have been completed. Pilot run might be occurred until Nov. depending on the international business progress.



Making A Safe, Effective and Cost-Conscious Vaccine, Available
for More Females Worldwide.....

– *Xiamen Innovax Biotech*

