PROJECT MANAGEMENT FOR POINT OF CARE TESTING

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LEARNING OBJECTIVES

1. Manage a project to implement a new point-of-care testing device.
2. Describe the steps needed to successfully manage implementation of new point-of-care testing devices.
3. Learn options for systems to manage projects.

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HYPOTHETICAL PROJECT

- A new urgent care center opening
- Requesting CBC, BMP, troponin, infectious disease testing, urine dipstick and pregnancy
- Will be connected to current middleware for result transmission and device/supply/operator management

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FIRST STEP

- A project charter should be developed
  - Can be simple or more complex, depending on the project
  - Should outline expectations
  - Clarify exactly what will be done
  - Project roles and responsibilities

PROJECT CHARTER

Should at least contain:

- Project owner
- Overview of project
- In scope/out of scope
- Timeline
- Budget
- Stakeholders

EXAMPLE

Project Charter

1. Introduction

This Project Charter formally authorizes the existence of the Presbyterian Hybrid ED/UC implementation project and provides the authority to proceed and apply organizational resources. The Project Charter reflects the goals and objectives of the project at a specific point in time. The project stakeholders are the intended audience for the document.

Business Need

Presbyterian is opening Hybrid ED/UC locations and will need lab services. The purpose of the project is to create and implement a point of care testing model that can be replicated to future locations. Presbyterian has contracted with LegacyER, who has established the hybrid business model in Texas. The project entails analysis, development, testing, implementation, training, and maintenance of the new hybrid business model.

Scope of Project

Validate instruments*
Integrate instruments with LIS*
Build and validate test menu*
Establish billing processes
Assist Presbyterian in obtaining CLIA certification
Establish pathology oversight
Train and certify TriCore POC & Presbyterian operator staff
**see Project Scope Document for list of instruments and tests*

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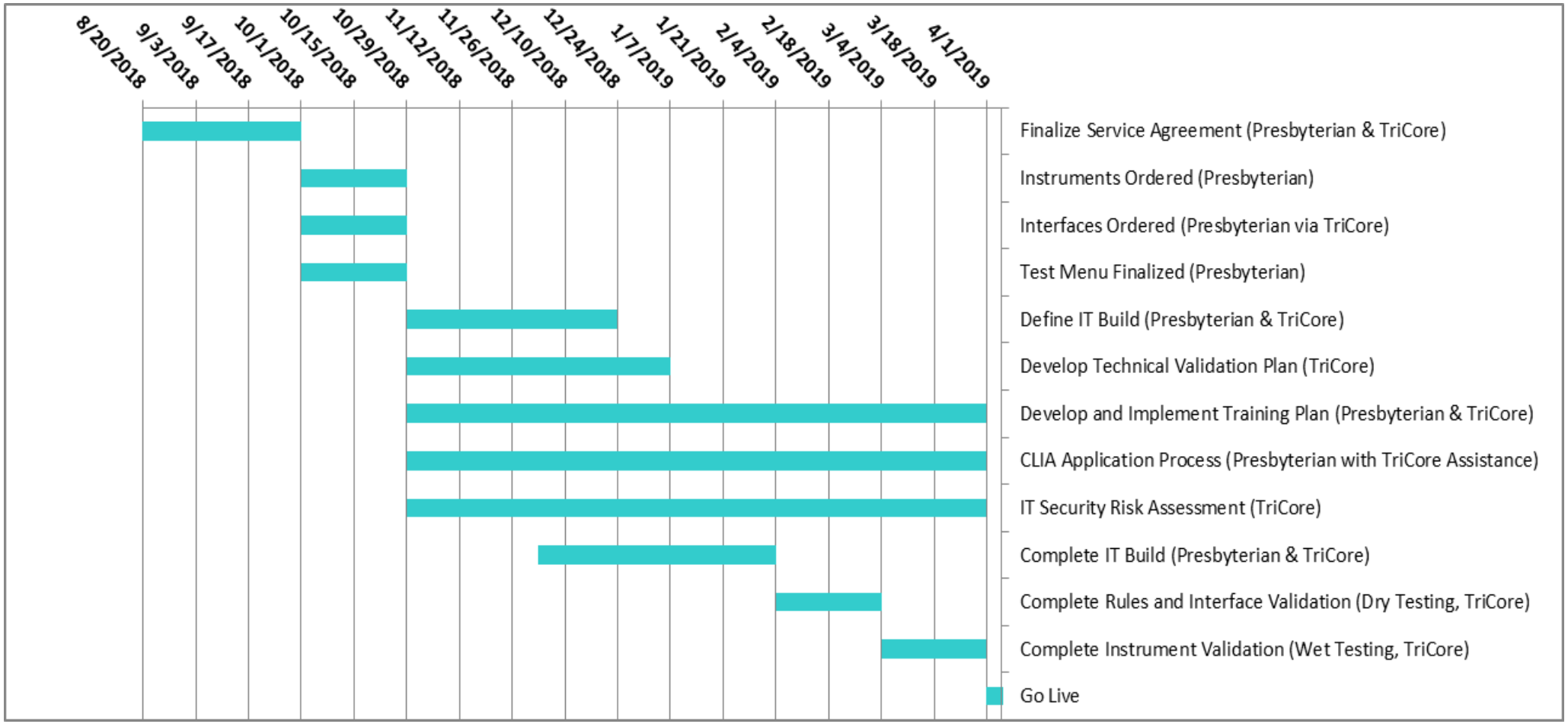
EXAMPLE

- **High Level Timeline**



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Project Management Software

- Microsoft project
- SmartSheets
- Basecamp
- GanttPro
- Excel

EXAMPLE

PresNow 24 7 UC ED Isleta	392 days?	4/1/2019	9/29/2020	18%			
Project Definition - Scope	340 days	4/1/2019	7/17/2020	25%			
WorkFlow	14 days	1/20/2020	2/6/2020	0%		TriCore POC[60%],Jeff [20%],Alwin[20%]	Should not change unless new test or devices are added
Regulatory certificates obtained	30 days	6/8/2020	7/17/2020	0%			CLIA, COLA, etc….
Define project timeline and milestone	30 days	11/4/2019	12/13/2019	100%		Pres[33%],Intuitive[33%],TriCore[33%]	
Drivers, order and results codes, defined	23 days	2/10/2020	3/11/2020	0%		Telcor[33%],TriCore[33%],Pres[33%]	Kathleen has on calendar
Vendor involvement - Telcor, Cobas etc….	20 days	4/2/2019	4/29/2019	0%			Need to move up! Kathleen to contact Telcor Feb 10th,
Site Identification, address,	28 days	4/1/2019	5/8/2019	0%		Pres[50%],Intuitive[50%]	Need address and phone number
Network Connectivity - define process with DH	5 days	12/9/2019	12/13/2019	0%		IT infrastruture[70%],Jeff [30%],Roman	
Test Menu Review	2 days	12/9/2019	12/10/2019	0%		Pres[33%],Intuitive[33%],TriCore[33%]	Already determined

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Physical location

- Is this a new build?
- Is it a renovation?
- What space is needed for devices?
- What space is needed for other equipment?
- What space is needed for supply storage?

Equipment

- What other equipment is needed?
  - Refrigerators
  - Freezers
  - Computer equipment
  - Centrifuges
  - Other

Regulatory Considerations

All labs in US need CLIA certificate

- Waived certificate
- Moderate complexity
- Provider performed microscopy

State regulations may be stricter than CLIA

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Regulatory Considerations

Other regulatory bodies

- CAP
- TJC
- COLA
- State DOH

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Personnel

- CLIA medical director
  - Additional requirements for mod complex testing
- Technical consultant for mod complex testing
- Clinical consultant for mod complex testing
- Requirements for testing personnel
  - PPM requirements

Device/Test List

- Decide what testing you would like to do
- Determine if POCT devices exist for that testing
- Does the method already exist in your department?
- Will you be sending out specimens for other testing
  - Will need specimen processing equipment and protocol

Supplies

- Needed for validation
- Needed for go live
- Needed for training
- Needed for ongoing quality control and semiannual studies
- Establish PAR levels for ongoing operation
- Ensure enough storage: room temp, refrigerated, etc.
- Proficiency testing

IT Considerations

- Is there an LIS/EMR that you will connect with?
- Middleware for connecting POCT devices
- Ports needed for connectivity
- Wi-fi
- Additional equipment (e.g., Lantronix box)
- How to enter results for manual tests

IT Test Builds

- Decide what IT test builds are needed
- Will need to build in LIS, middleware, and EMR/HIS
- How are the submissions done for your site?
- Builds necessary for:
  - New location
  - New devices
  - New test panels

Middleware considerations

- Location build
- New tests need to be built in the system
- Enter devices
- Enter all applicable parameters: consumables
- Enter operators and grant access to devices

Clinical Validation

- Depends on whether waived or moderately complex
- At minimum for waived, follow manufacturer's instructions
- For moderate complexity, minimum is:
  - Accuracy
  - Precision
  - Reportable range
  - Normal range

Clinical Validation

- If part of a system, compare new methods and current method with patient specimens
- Write a validation protocol, approve by CLIA medical director
- Determine time frame to allow for all activities and sign-offs

IT Validation

- Run every panel (in Test mode)
- Check numerical or semi-quantitative/qualitative results
- Check reference intervals
- Check units
- Check interpretive and other comments
- Ensure regulatory compliance with test report
- Obtain approval: medical director and IT department

Documentation

- Procedures
- Training checklists
- Learning program modules
- Logs for QC, maintenance, environmental checks
- Job aids

Training

- Determine who will train operators
- Checklists for all devices/kits
- Vendors can assist
- Middleware: add operators and permit access
- Need a plan for ongoing competency assessment-assign in middleware?

GO LIVE!

- Obtain all change board/committee approvals for go live
- Move all builds from Test to Production
- Have all parties available for date/time of go live to address any issues that arise
- Perform IT production validation to ensure everything that was tested is the same in Production
- Monitor for appropriate amount of time after go live
- CELEBRATE!

Multiple Projects

Wouldn’t it be wonderful if we only had one project going on at a time?

However, that’s not how it happens. So, in addition to managing individual projects, a process is needed for keeping track of multiple projects.

Example

Project name	Site	Project owner	Started?	ID	Title SCR	Assigned	Proposed go live	Comments
Quantra add device	Pres downtown	Ashlee Tezak	Yes	2652	12086	Isaac	4/5/2023 (April sprint)	LIVE!
New location build	Medicare Advantage Clinic/Winrock	Lex Lubchenco	Yes	2888	12223		8/1/2023	Site will open in august
ID Now add device/new location build	Pan American Peds and MAC	Lex Lubchenco	No	2955			TBD	Pan Am Peds and Pan Am Medicare Advantage Clinic are in the same building and share the same CLIA. The ID Now build for Peds and the Medicare Advantage clinic will be the same build.
HMS add device	Pres downtown	Ashlee Tezak	No	2894	12232	Isaac	6/14/2023 (June sprint)	new SCRs put in for individual tests; 3058, 3059 and 3060
Quantra add device	UNMH	Charles Yaple	Yes	1949	11027	Isaac	6/14/2023 (June sprint)	device and test build same as PH; needs Cerner TCM. Assigned to Isaac

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QUESTIONS?

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