LIS Contracting, Implementation and Workflow Design

Alexis Carter, MD

Director of Pathology Informatics

Department of Pathology and Laboratory Medicine

Department of Biomedical Informatics

Emory University School of Medicine

Disclosures

- No financial disclosures to report

Reminders

- For Pathology Informatics 2014, use **#PathInfo2014** on Twitter

Disclaimers

- *RE: the contract portion of this talk…*
  - *I am NOT an attorney*
  - *Provided as a convenience*
  - *Does NOT represent legal advice*
  - *Contracts should be reviewed by an attorney, and any questions about your specific contract should be directed to official counsel.*

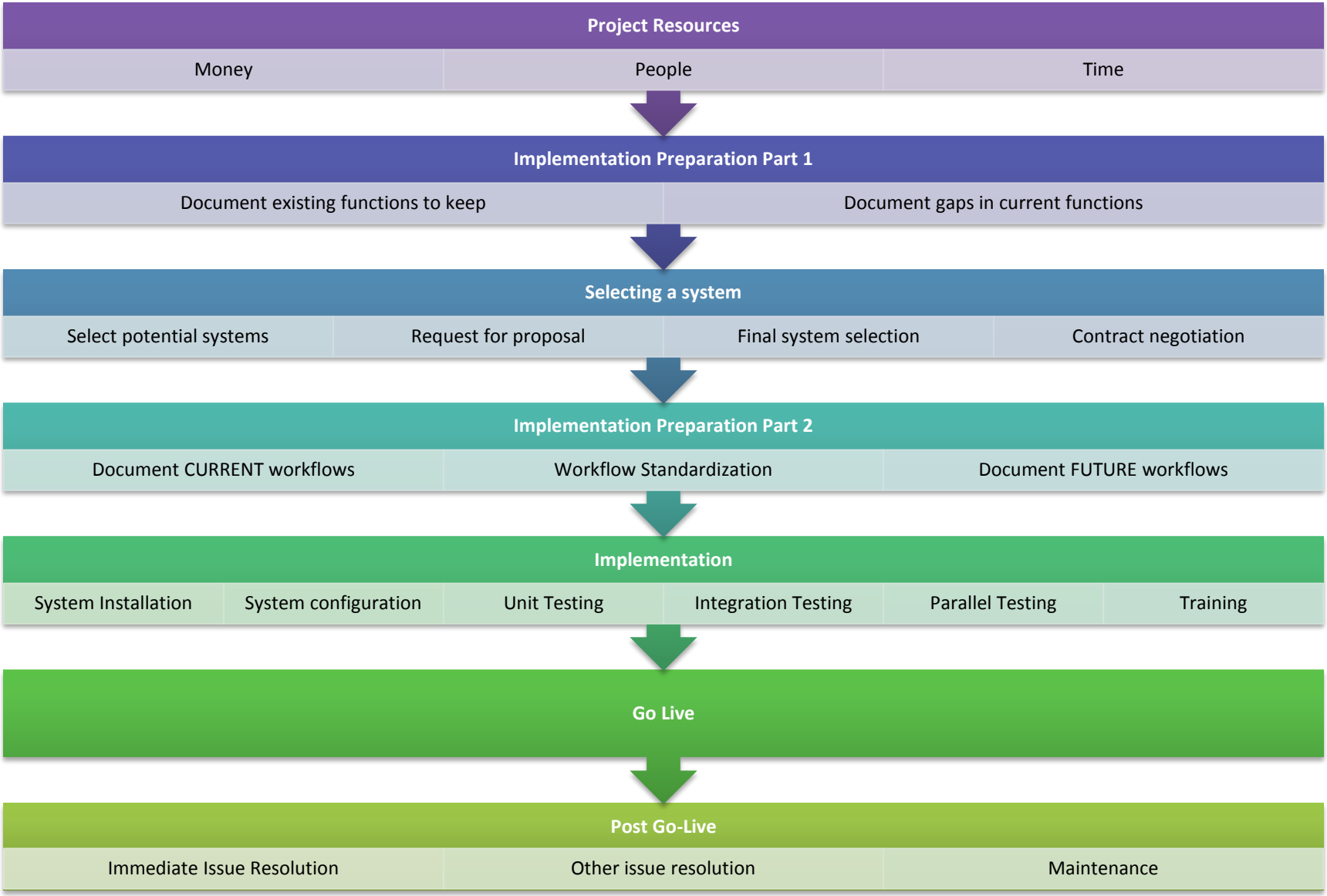
So, you've decided to get a new LIS…

Objectives

- Describe preparatory steps to the go-live of a new LIS
- Understand why those preparatory steps are important
- Understand the importance of reviewing (and knowing who is reviewing) the **contract** for the new LIS (often overlooked until too late)

Abbreviations

Abbreviation	Meaning
LIS	Laboratory Information System
EHR	Electronic Health Record
SME	Subject Matter Expert



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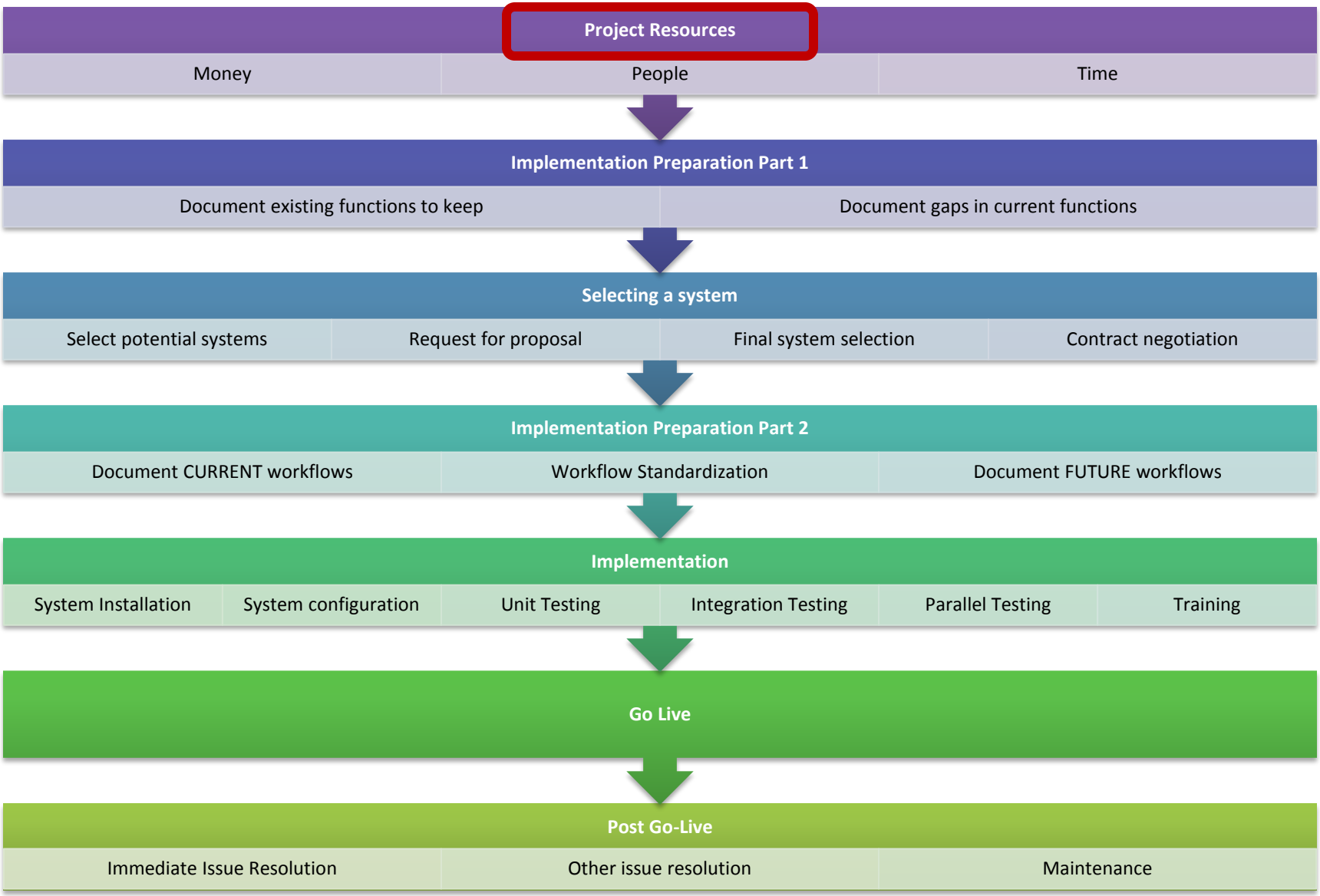

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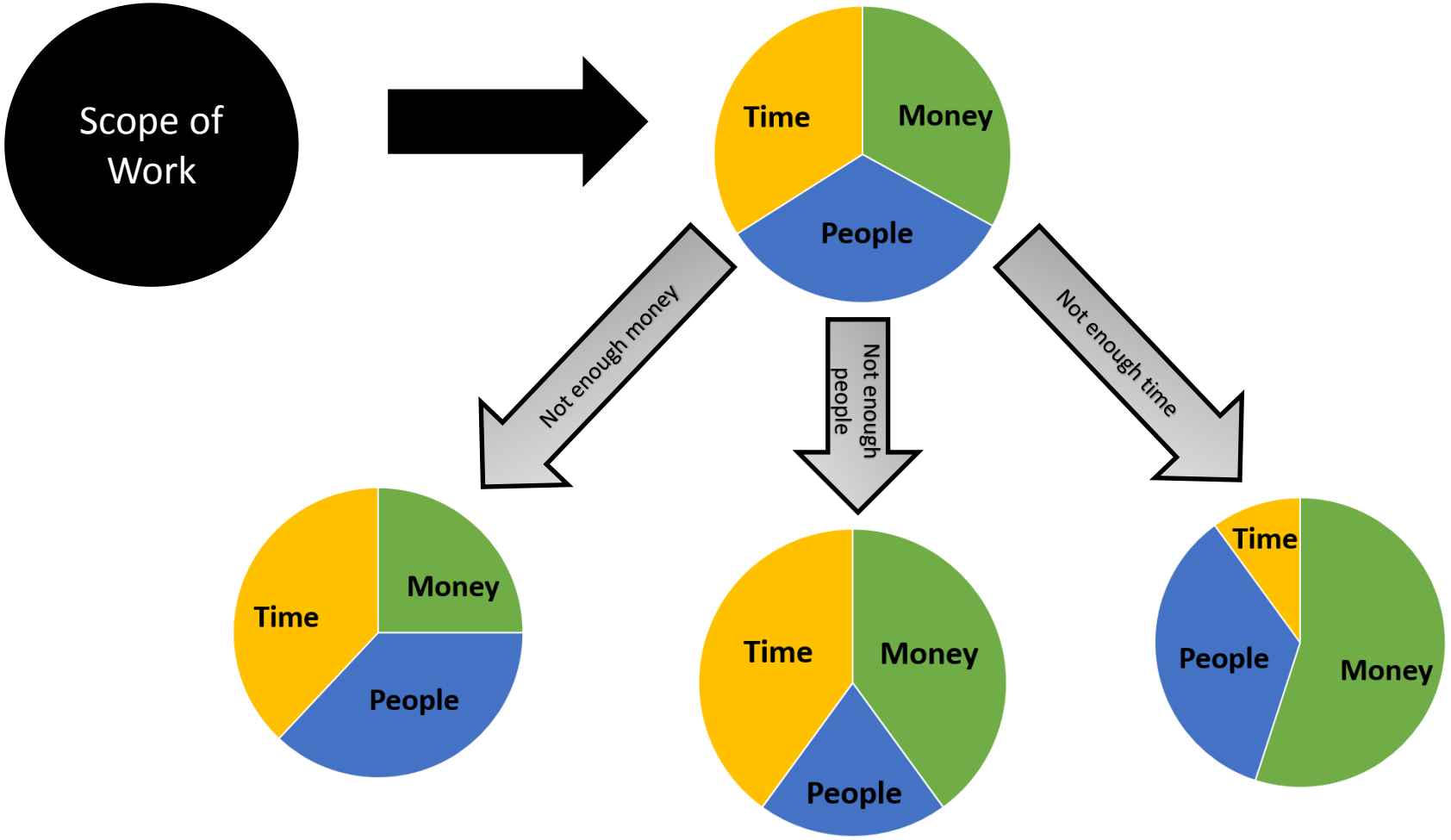
Project Resources

- Successful projects require
  - Money
  - People
  - Time

Project Resources



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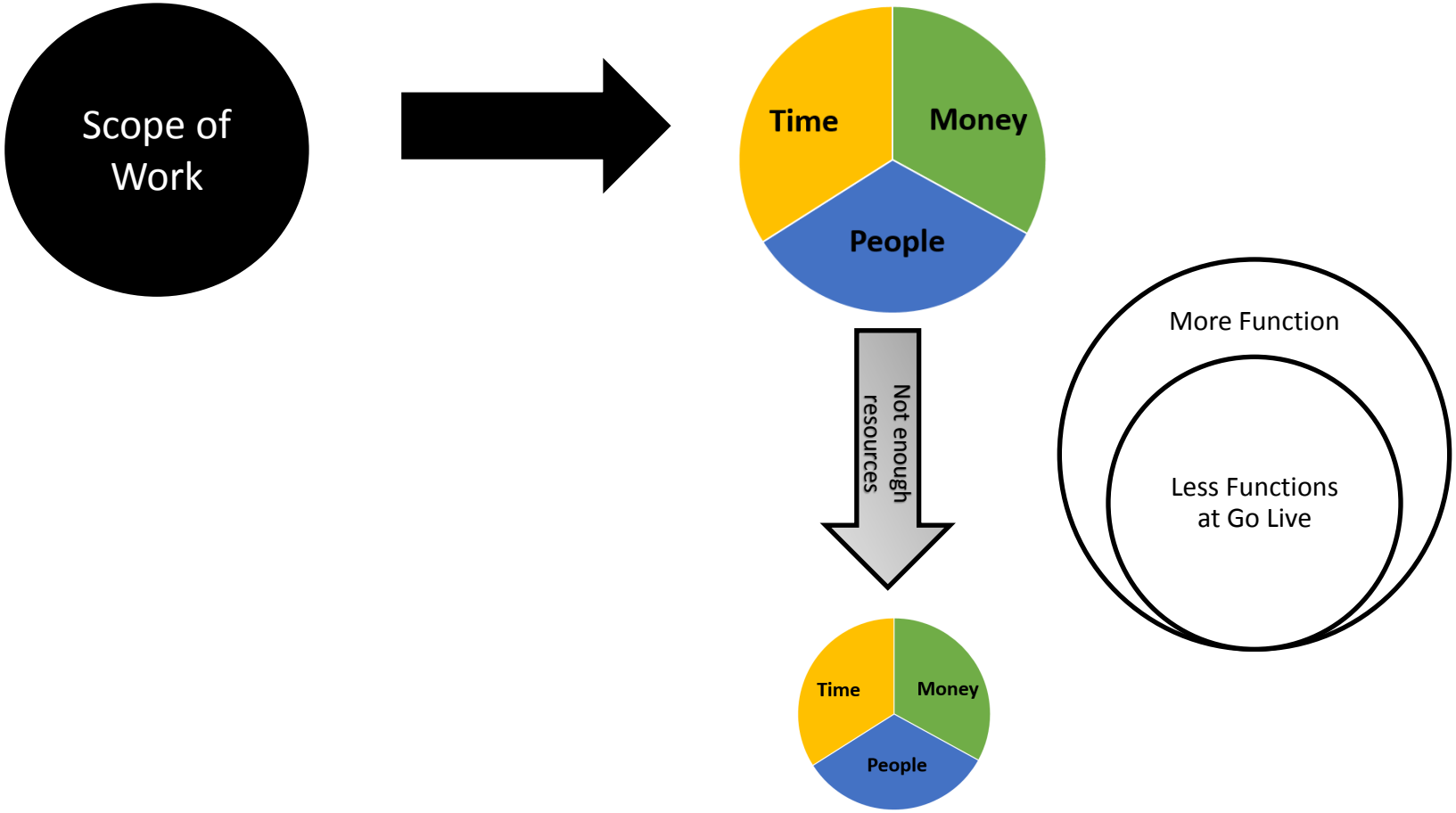
Project Resources



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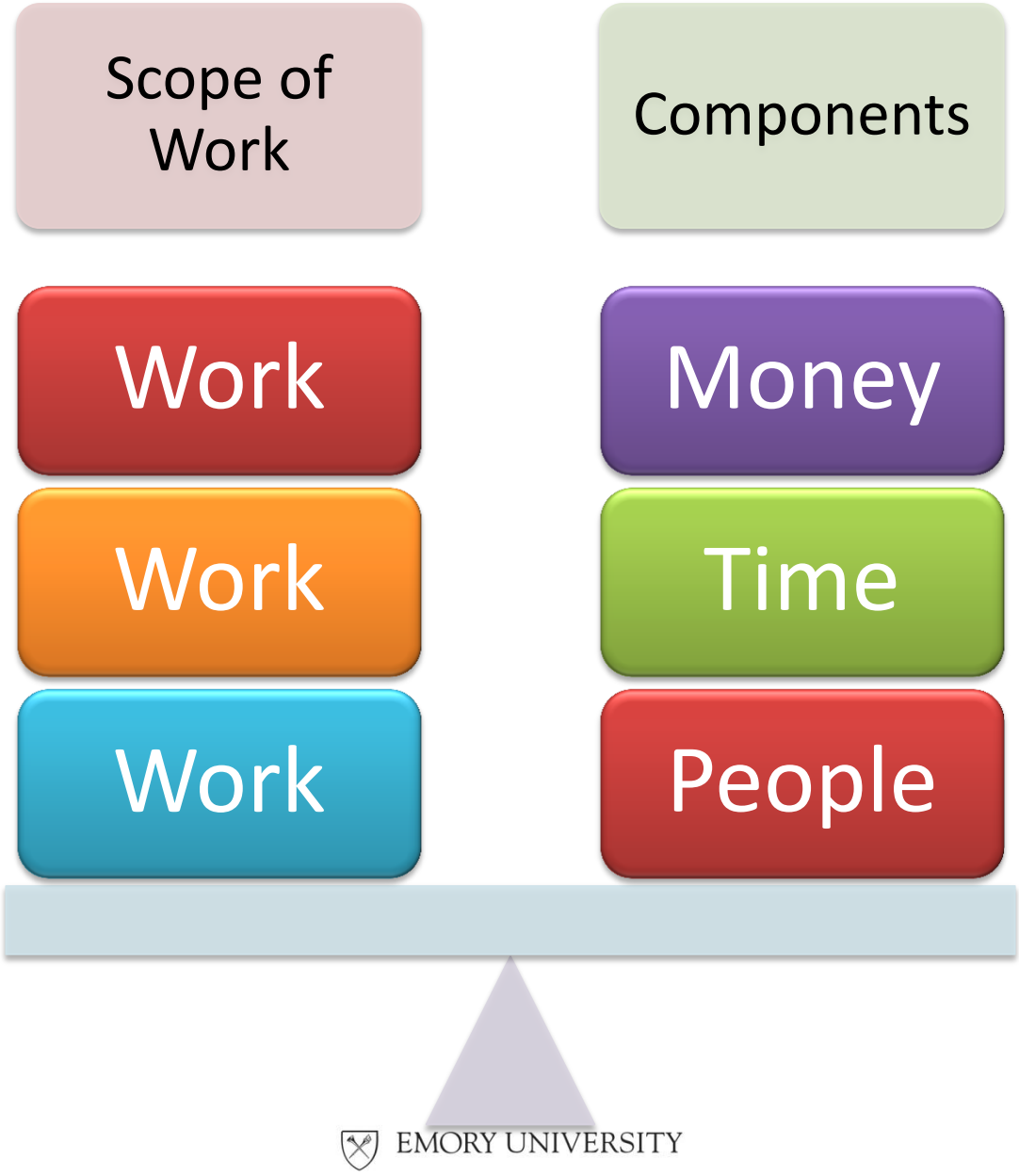

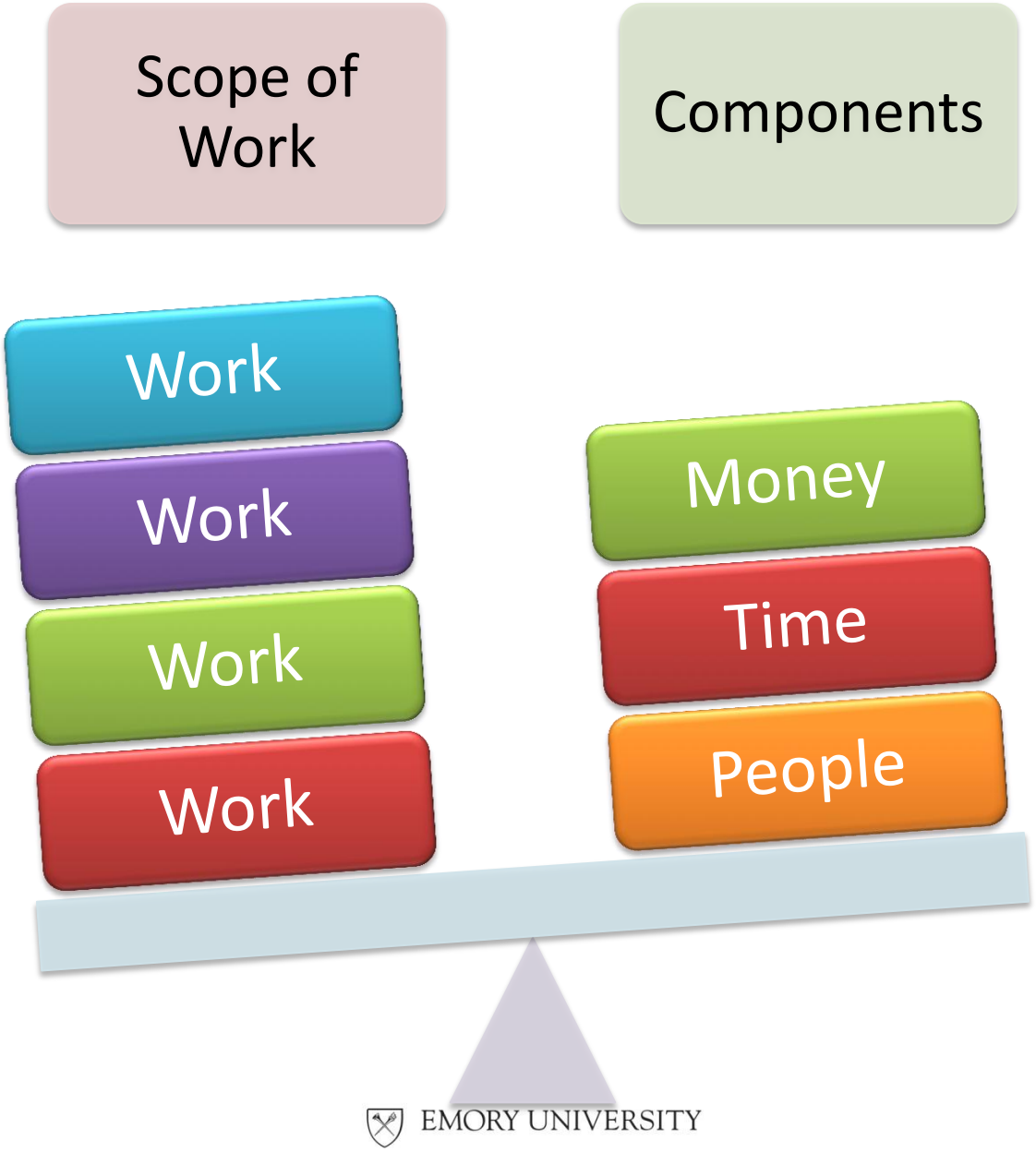

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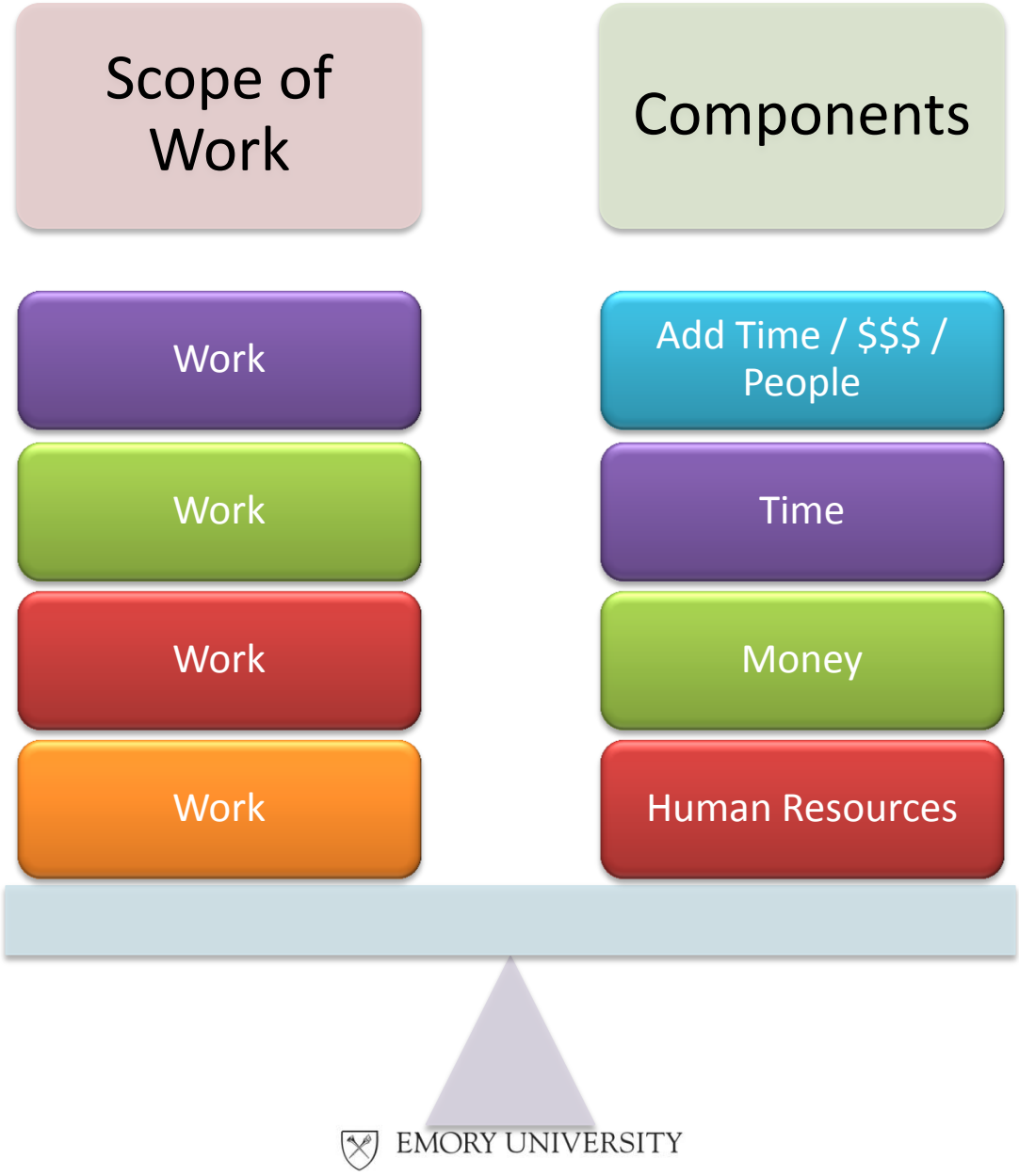
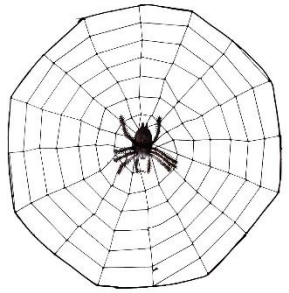


A word on People…

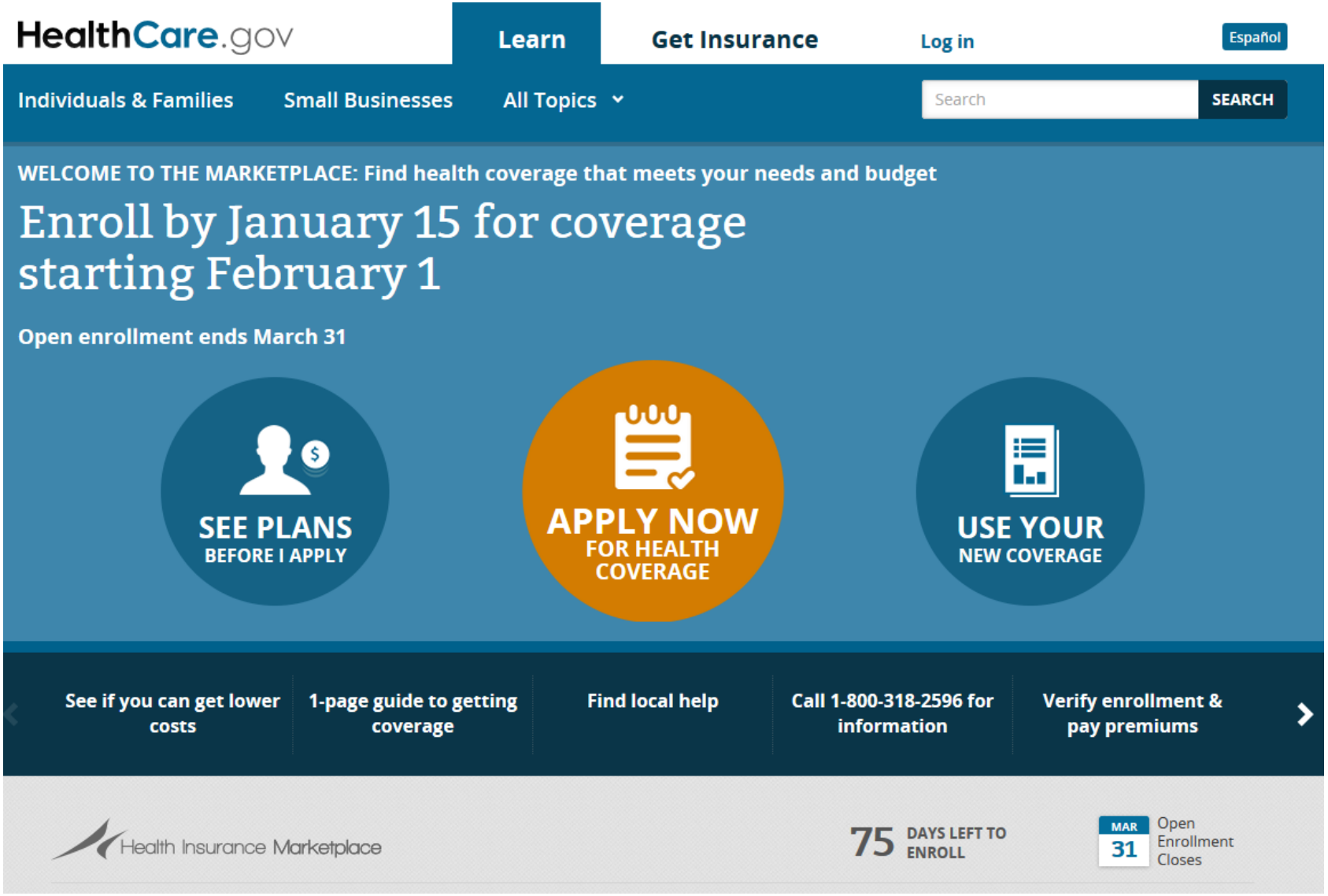
- Hire a good project management professional (PMP)
  - Ensures that project delivers expected product, on time, under budget
  - Ensures that tasks are clearly assigned
  - Ensures that tasks are being completed
  - Is the spider at the center of the project's web
  - *If the PMP isn't annoying you, is he/she doing the job?*
  - Should NOT be an employee of the LIS vendor



A word on People…

- Here are the other people you need…
  - Champions (Pathologist, PhD professionals, administrators)
  - Medical Directors
  - Laboratory SuperUsers (SMEs)
  - Informatics specialists
  - IT resources (LIS team, Core teams, Network specialists)
  - Vendor resources (SMEs for the LIS)
- They need PROTECTED TIME to do this implementation
- **Get them off site and away from laboratory (if possible)**

PROJECTS GONE WRONG…



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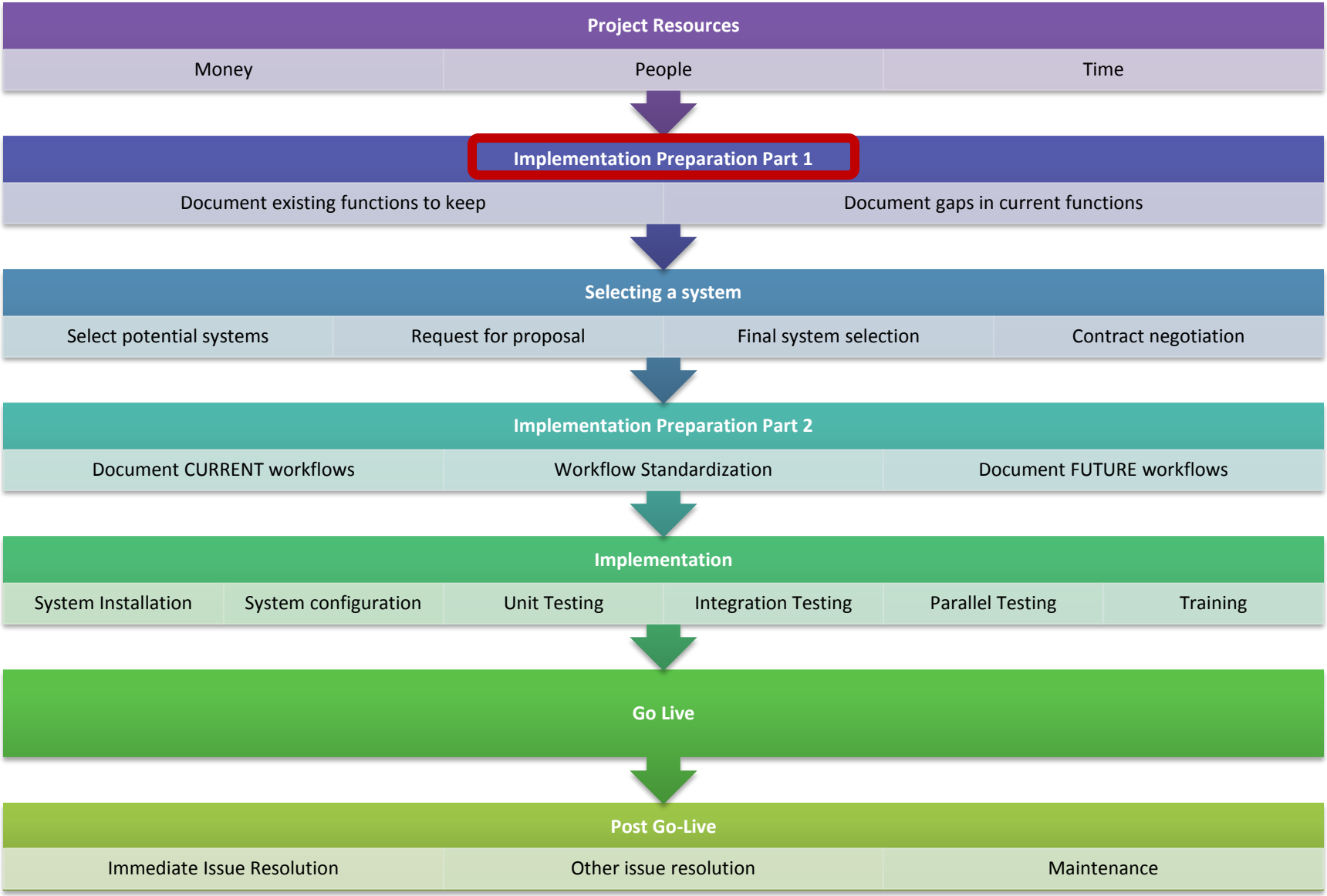
How did it happen?

	Obama Campaign	Healthcare.gov
Scope (Complexity) of Work	Simple	Highly complex
Selection of vendor	Based on quality	Required to use the lowest bidder in a federal contracting process
Vendors used	Facebook, Twitter and Google and others	CGI Federal (a Canadian company) and QSSI
Time	Lots	Not so much
Money	Flexible	Not flexible
People	Under direct control	Belonged to vendors
Project Managers	Tight cohesion	Many PMPs, lacked cohesion



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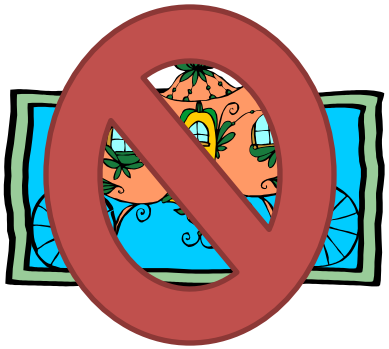
Implementation Preparation Part 1

- **Document** existing LIS functions
  - SME
  - LIS Team
  - Reports, Queries, Printing



Don't know what you got, until it's gone…

Cinderella

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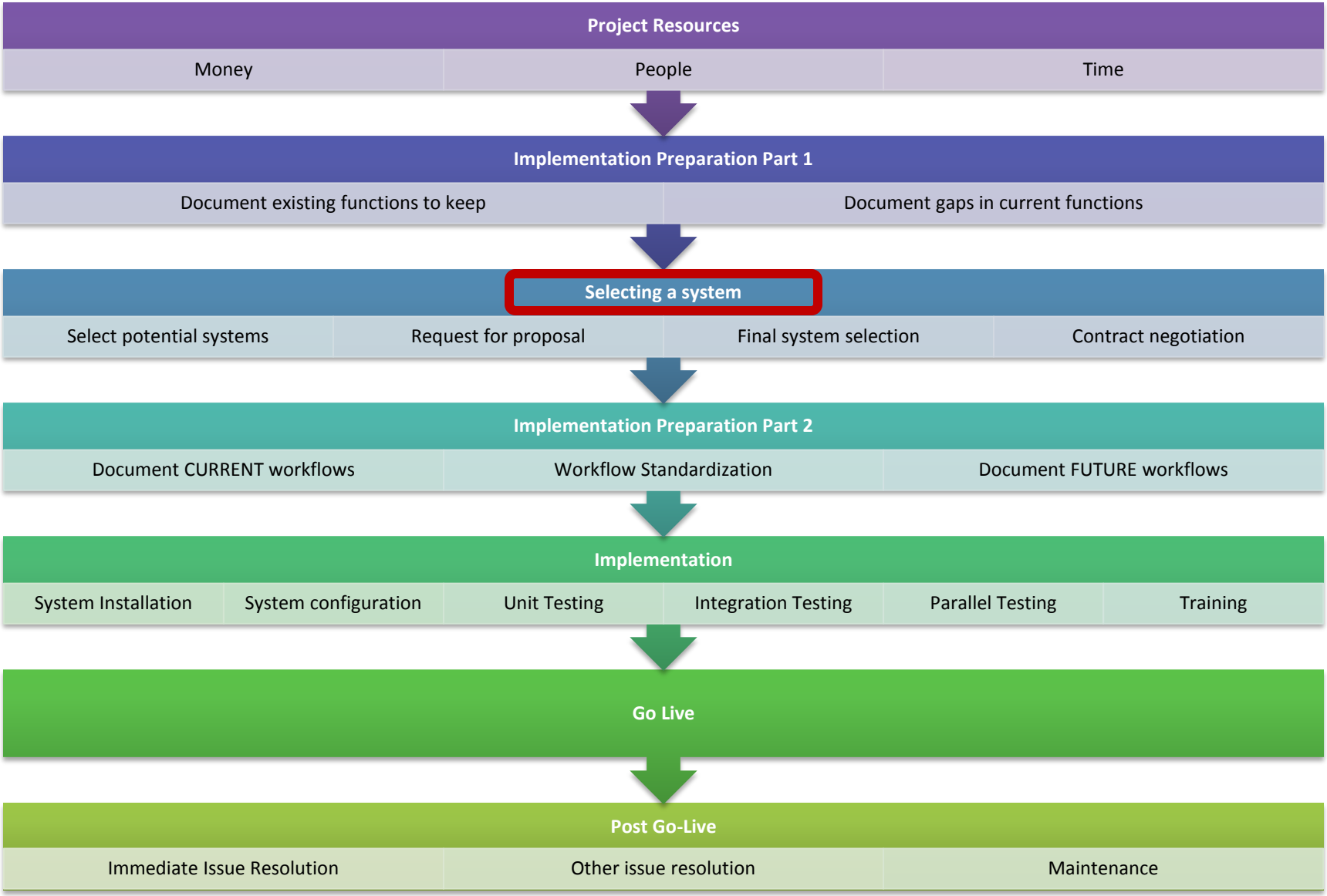
Implementation Preparation Part 1

- **Document** gaps in existing functionality
  - Must have
  - Nice to have
- "Must Haves" = mustn't be without. Includes:
  - Current functionality AND/OR
  - Patient safety issue AND/OR
  - Compliance issue AND/OR
  - Significant negative financial impact
- "Nice to have" = negotiable

Implementation Preparation Part 1 (cont.)

- Know what you need now
- Know what you think you need
  - Five years from now
  - Ten years from now
- Special laboratory needs?
  - Special = highly complex and unique workflows
  - Workflows don't fit well with plain vanilla LIS
  - HLA, Flow, Molecular/Genomics, Cytogenetics, etc.



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Selecting a System

- Select systems for further study
  - CAP Today
- Construct and send Request for Proposal (RFP)
  - Different from Request for Information (RFI)
  - Formal process
  - You WILL make a selection at the end

Final System Selection

- Review returned RFPs
- Compare systems
- Make final selection
- Enter into contract negotiations
- **Retain attorney specializing in healthcare information system/software contracts**

Contract Review Process

- You need a checklist and an attorney

March 2013
Editors:
Raymond D. Aller, MD
Hal Weiner

LIS purchase contracts: a bore you can't ignore
Admit it: even the mere thought of reading a purchase contract for a laboratory information system makes your eyes glaze over. Turgid legalese aside, the sheer length and level of detail of the document makes the process painful, said Alexis B. Carter, MD, director of pathology informatics in the Department of Pathology and Laboratory Medicine, Emory University Hospital System, Atlanta. Nevertheless, she said, "With contracts, the devil really is in the details, and I can't stress enough that if you're not going to read it yourself, you need to have someone do it who understands your day-to-day needs."

Phases of contract review

- Select system
- Do your homework
- Check the items received for review
- Review the contract
- Provide feedback to your attorney

Contract - Homework

- User Licenses
  - Total number of users vs. Concurrent users
- Hosting and support of hardware
- Number and type of interfaces
  - EHRs
  - Interface portals and patient portals
  - Reference labs
  - Instruments and middleware

Contract - Homework

- How will backups occur?
  - Institutional backup management system?
- Images
  - Do you need image management?
  - How will the images be acquired? Gross photos vs. photomicrographs vs. imported from an instrument (e.g., electropherogram)?
  - How will the images be used?

Contract - Homework

- Data migration and access to old data
  - Do you need data migration?
    - Anatomic Pathology
    - Blood bank
    - HLA and Compatibility Testing
  - Reminder: You do need to have access to the old data per CLIA for a period of time.

Contract - Homework - Who

- Determine ahead of time
  - You?
  - Your LIS team?
  - Subject matter experts for the lab(s) using the system after go-live?
  - The laboratory medical director?
  - Any other IT personnel?
  - Your **attorney** should **ALWAYS** review your contracts!

You received the contract

- Check table of contents
- Check for missing parts
- Request missing parts
  - Could be critical!

Reviewing the contract

- Statements of compliance with…
  - Regulations
    - CLIA
    - HIPAA
    - FDA
  - Standards
    - CAP, TJC
    - ISO, CLSI
    - DICOM, Barcoding symbologies
    - LOINC, SNOMED, ICD-9/10, CPT, etc.

Contract - Scope of Work

- Reality check
  - All sites included
  - Vendor work expectations vs. client work expectations
- Deadlines
  - What if you don't meet them?
  - What if the vendor doesn't meet them?

Contract - Term and Termination

- Term
  - For what period is the contract in effect?
  - Does it expire if specific actions don't take place?
- Termination
  - By the vendor
  - By you
  - For cause or without cause
  - Going out of business (you or vendor)

Contract - Uptime

- Percent uptime should be included
- Is this percent uptime acceptable for the LIS in question?
- What happens if the system isn't up at its expected threshold?
- What exceptions are given for system uptime?
  - Maintenance downtimes
  - End-user tampering/crashing

Contract - Support and Maintenance

- When available? 24/7?
- What's the turnaround time on support?
  - During unexpected downtime?
- What is supported?
  - Hand-holding
  - Software
  - Hardware
- What type of support?
  - Phone calls, email, on site visits
- Are there extra charges for support if you go above a certain time limit?

Contract - Support and Maintenance

- Updates
  - How frequently are you required to take them?
  - What happens if you don't?
  - Need to balance staying up to date with resource management

Contract - Data migration

- Included?
- Will it be migrated by go-live?
  - If not, when? (Hint: you need a deadline)
- Access to old data included?
  - Need deadlines for this also

Contract - Images

- Included?
- Is specific hardware or instruments required?
- Can it take images from your existing equipment?

Contract - Backups

- Automated backups included?
- Is the mechanism compatible with your institution's requirements, if any?
- Where will the backup files be stored?
- Are they secure?

Contract - Non-disclosure clauses

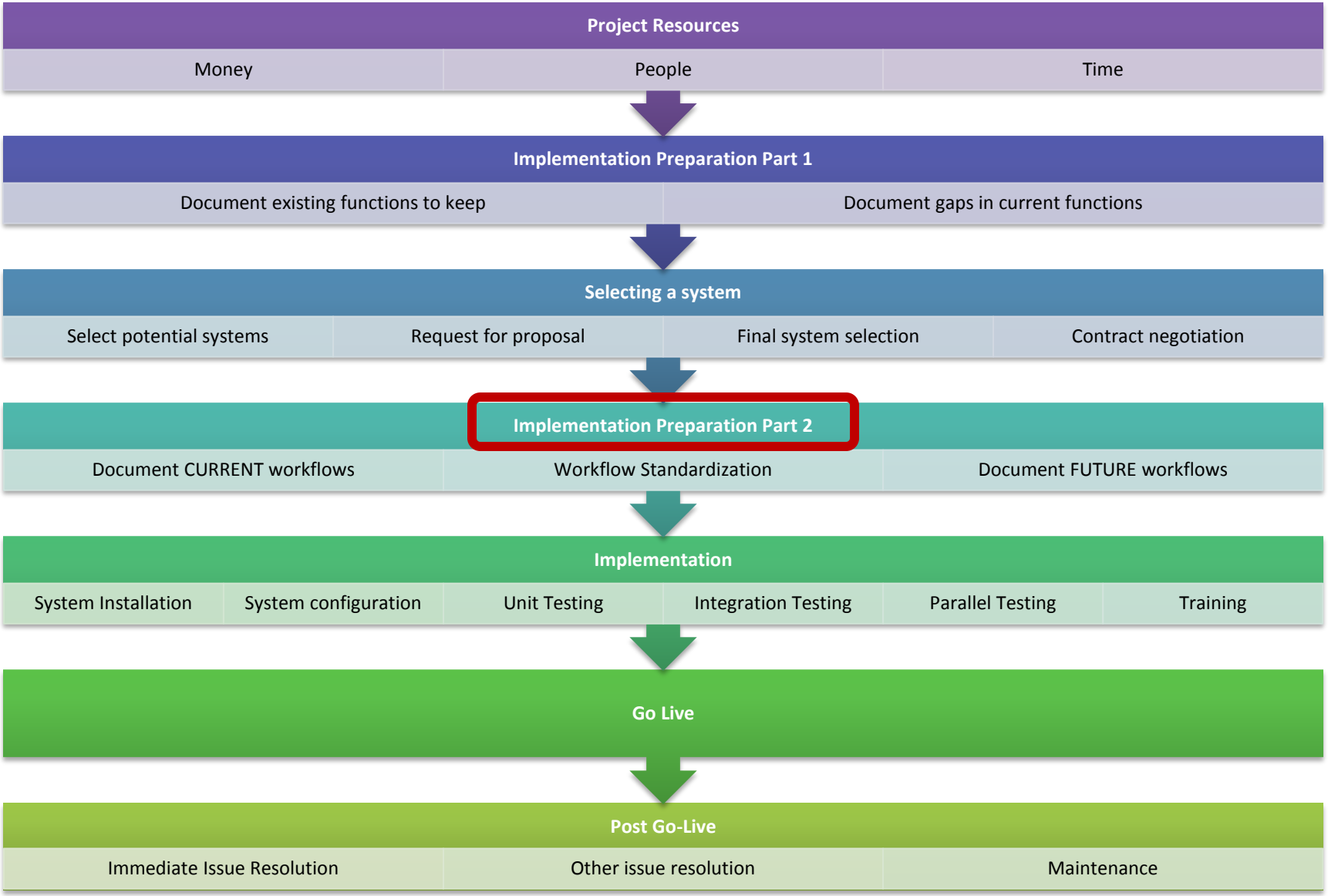
- What can you NOT disclose about the company?
- What can the company NOT disclose about you or your patients?
  - Business Associate Agreement (BAA)

Contract - Payment

- How and when are you supposed to pay them during implementation?
  - Is this reasonable?
- Price increases?
  - Are they capped?
  - How much notice do you get?
- Suggestion
  - 30% payment at contract signature
  - 30% at go-live
  - 40% at “acceptance”

Contract - Comparing against RFP

- Compare functions listed as standard in RFP to functions listed in contract
  - Are there mismatches?
- Recalculate five-year costs
  - Get any discrepancies explained and fixed



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Implementation Preparation Part 2 - WORKFLOW

The first rule of any technology used in a business is that **automation applied to an efficient operation will magnify the efficiency**.

The second is that **automation applied to an inefficient operation will magnify the inefficiency**.

Bill Gates

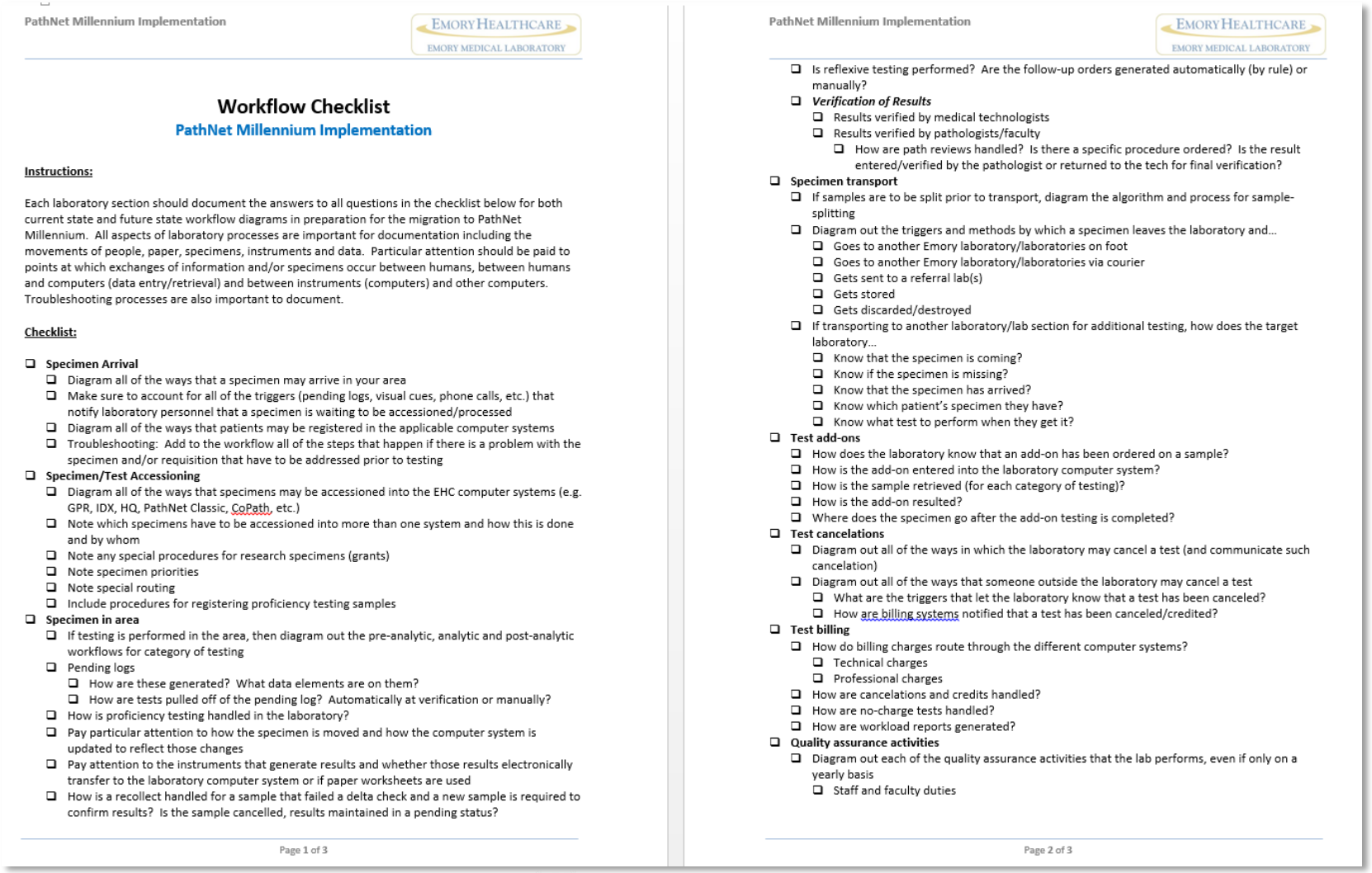
Implementation Preparation Part 2

- DOCUMENT your current workflows
  - We're doing what?!! (Expect some surprises)
  - What do you mean we are doing the same thing three times? (Expect some inefficiencies)
  - How do you know that this specimen has not been collected yet? (Figure out where workflow triggers are missing)

Document Current Workflows

- SME in each laboratory to complete
  - Signed off by medical director
- Use a checklist!
- (Don’t forget that your LIS team also needs to complete one for themselves)

Document Current Workflows



PathNet Millennium Implementation

EMORY HEALTHCARE
EMORY MEDICAL LABORATORY

Workflow Checklist

PathNet Millennium Implementation

Instructions:

Each laboratory section should document the answers to all questions in the checklist below for both current state and future state workflow diagrams in preparation for the migration to PathNet Millennium. All aspects of laboratory processes are important for documentation including the movements of people, paper, specimens, instruments and data. Particular attention should be paid to points at which exchanges of information and/or specimens occur between humans, between humans and computers (data entry/retrieval) and between instruments (computers) and other computers. Troubleshooting processes are also important to document.

Checklist:

- ❑ **Specimen Arrival**
  - ❑ Diagram all of the ways that a specimen may arrive in your area
  - ❑ Make sure to account for all of the triggers (pending logs, visual cues, phone calls, etc.) that notify laboratory personnel that a specimen is waiting to be accessioned/processed
  - ❑ Diagram all of the ways that patients may be registered in the applicable computer systems
  - ❑ Troubleshooting: Add to the workflow all of the steps that happen if there is a problem with the specimen and/or requisition that have to be addressed prior to testing
- ❑ **Specimen/Test Accessioning**
  - ❑ Diagram all of the ways that specimens may be accessioned into the EHC computer systems (e.g. GPR, IDX, HQ, PathNet Classic, CoPath, etc.)
  - ❑ Note which specimens have to be accessioned into more than one system and how this is done and by whom
  - ❑ Note any special procedures for research specimens (grants)
  - ❑ Note specimen priorities
  - ❑ Note special routing
  - ❑ Include procedures for registering proficiency testing samples
- ❑ **Specimen in area**
  - ❑ If testing is performed in the area, then diagram out the pre-analytic, analytic and post-analytic workflows for category of testing
  - ❑ Pending logs
    - ❑ How are these generated? What data elements are on them?
    - ❑ How are tests pulled off of the pending log? Automatically at verification or manually?
  - ❑ How is proficiency testing handled in the laboratory?
  - ❑ Pay particular attention to how the specimen is moved and how the computer system is updated to reflect those changes
  - ❑ Pay attention to the instruments that generate results and whether those results electronically transfer to the laboratory computer system or if paper worksheets are used
  - ❑ How is a recollect handled for a sample that failed a delta check and a new sample is required to confirm results? Is the sample cancelled, results maintained in a pending status?

Page 1 of 3

PathNet Millennium Implementation

EMORY HEALTHCARE
EMORY MEDICAL LABORATORY

- ❑ Is reflexive testing performed? Are the follow-up orders generated automatically (by rule) or manually?
- ❑ ***Verification of Results***
  - ❑ Results verified by medical technologists
  - ❑ Results verified by pathologists/faculty
    - ❑ How are path reviews handled? Is there a specific procedure ordered? Is the result entered/verified by the pathologist or returned to the tech for final verification?
- ❑ **Specimen transport**
  - ❑ If samples are to be split prior to transport, diagram the algorithm and process for sample-splitting
  - ❑ Diagram out the triggers and methods by which a specimen leaves the laboratory and…
    - ❑ Goes to another Emory laboratory/laboratories on foot
    - ❑ Goes to another Emory laboratory/laboratories via courier
    - ❑ Gets sent to a referral lab(s)
    - ❑ Gets stored
    - ❑ Gets discarded/destroyed
  - ❑ If transporting to another laboratory/lab section for additional testing, how does the target laboratory…
    - ❑ Know that the specimen is coming?
    - ❑ Know if the specimen is missing?
    - ❑ Know that the specimen has arrived?
    - ❑ Know which patient's specimen they have?
    - ❑ Know what test to perform when they get it?
- ❑ **Test add-ons**
  - ❑ How does the laboratory know that an add-on has been ordered on a sample?
  - ❑ How is the add-on entered into the laboratory computer system?
  - ❑ How is the sample retrieved (for each category of testing)?
  - ❑ How is the add-on resulted?
  - ❑ Where does the specimen go after the add-on testing is completed?
- ❑ **Test cancelations**
  - ❑ Diagram out all of the ways in which the laboratory may cancel a test (and communicate such cancelation)
  - ❑ Diagram out all of the ways that someone outside the laboratory may cancel a test
    - ❑ What are the triggers that let the laboratory know that a test has been canceled?
    - ❑ How are billing systems notified that a test has been canceled/credited?
- ❑ **Test billing**
  - ❑ How do billing charges route through the different computer systems?
    - ❑ Technical charges
    - ❑ Professional charges
  - ❑ How are cancelations and credits handled?
  - ❑ How are no-charge tests handled?
  - ❑ How are workload reports generated?
- ❑ **Quality assurance activities**
  - ❑ Diagram out each of the quality assurance activities that the lab performs, even if only on a yearly basis
    - ❑ Staff and faculty duties

Page 2 of 3

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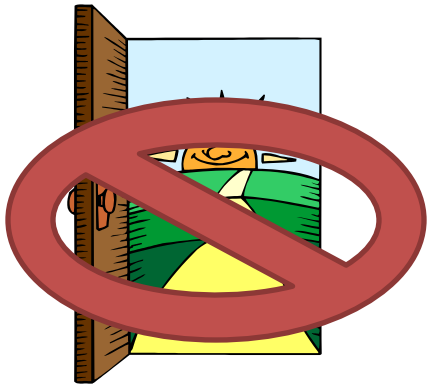
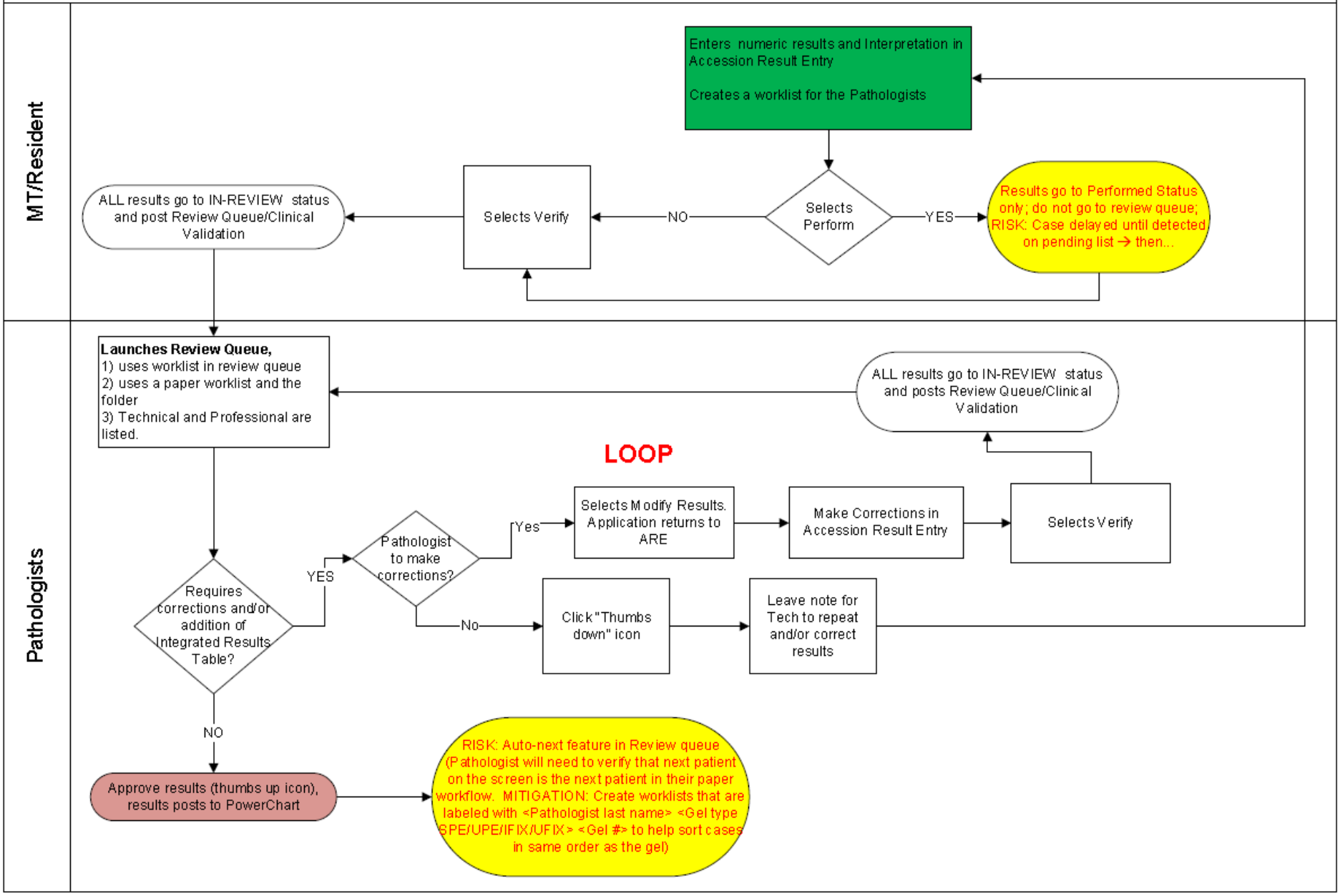
Document Current Workflows

- Use Diagrams
- Swim lane diagrams very helpful
  - Each swim lane is a job position
  - Very good identifier of points of inefficiency
  - Do NOT just document the happy path…



Review Queue (not using the Integrated Results Table)

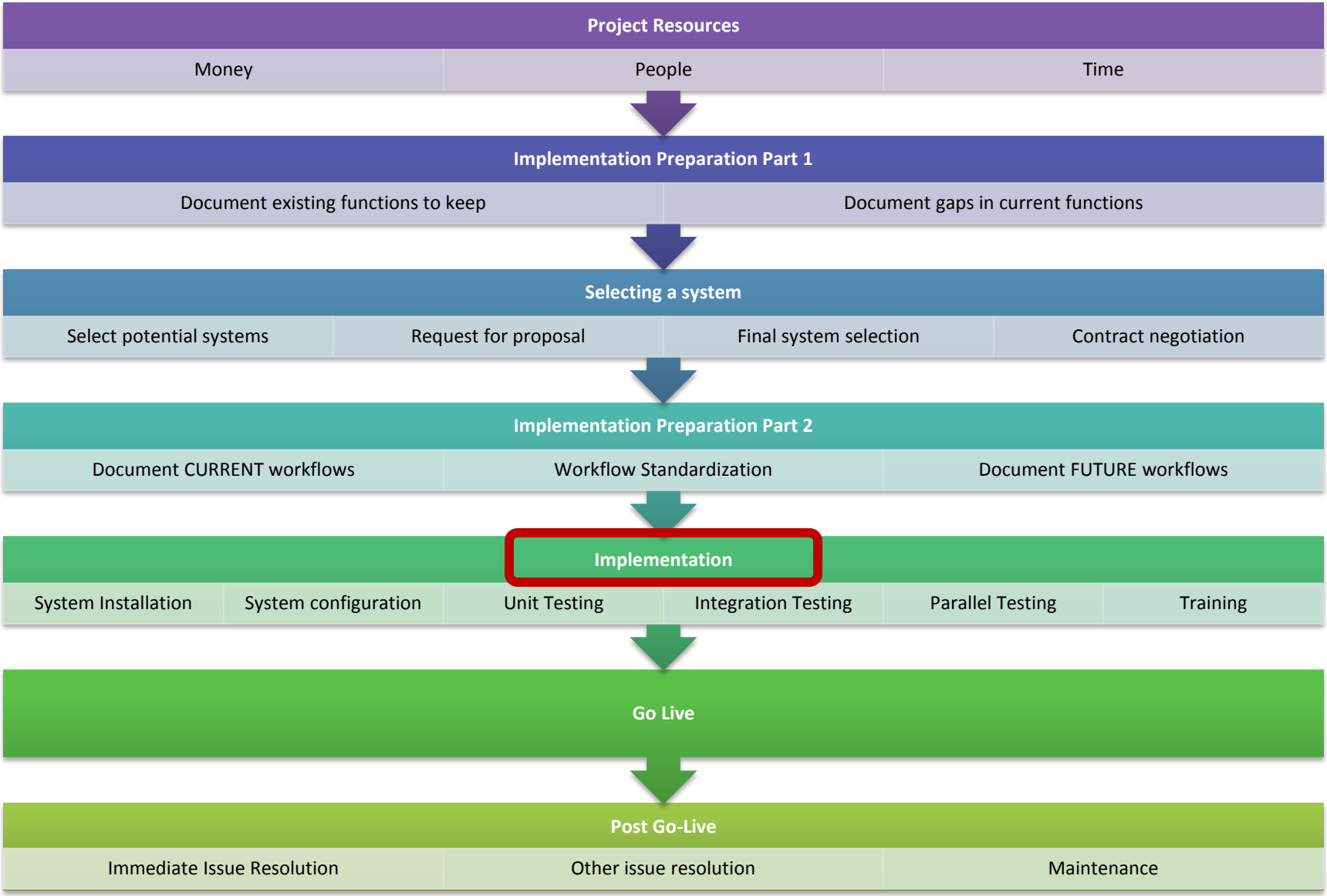


Workflow Standardization

- Documentation of current workflow will unearth non-standard work
- LIS implementations go a lot better if work is standardized (everyone does the same process for the same work)
- Needs to happen **PRIOR** to (and not at) your go-live
- Needs to keep the future state in mind

Document DRAFT future workflows

- Warn users that final workflows WILL be different as knowledge of the new LIS evolves
- Use swimlane diagrams
- Do not start writing procedures yet



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Implementation

- System Installation
  - Vendor installs hardware and software
- System configuration
  - Configure options
  - Upload dictionaries
- Unit Testing
  - Testing of application within itself

Implementation

- Integration Testing
  - Testing of application's communications with other systems (interfaces)
  - Orders, Results, Billing, Demographics
  - Middleware, instruments, EHRs, Billing systems, Registration systems, reference laboratories
  - Data migration efforts should be under way

Implementation

- Parallel Testing
  - "dry run" of doing work on real patients in new system while doing same work in current system
  - 20% of cases is ideal
  - Very strenuous for everyone but makes go live a LOT easier
  - Very important to do if possible

Implementation

- Train end-users / final stages
  - SuperUsers and IT resources develop go-live coverage schedules
  - Supervisors write new procedures
  - Prep for Go-Live
  - Disseminate go-live schedules, escalation policies, 24/7 call line numbers
  - HAVE A BACKOUT PLAN

Go-Live

- Things will go wrong at go-live
- The number and scope of things are inversely proportional to how much you prepared
- Testing (especially parallel testing) is critical
- Beware of bringing on a lab system into an existing EHR platform
  - Inhibits testing
- Sometimes things happen outside your control

QUESTIONS?