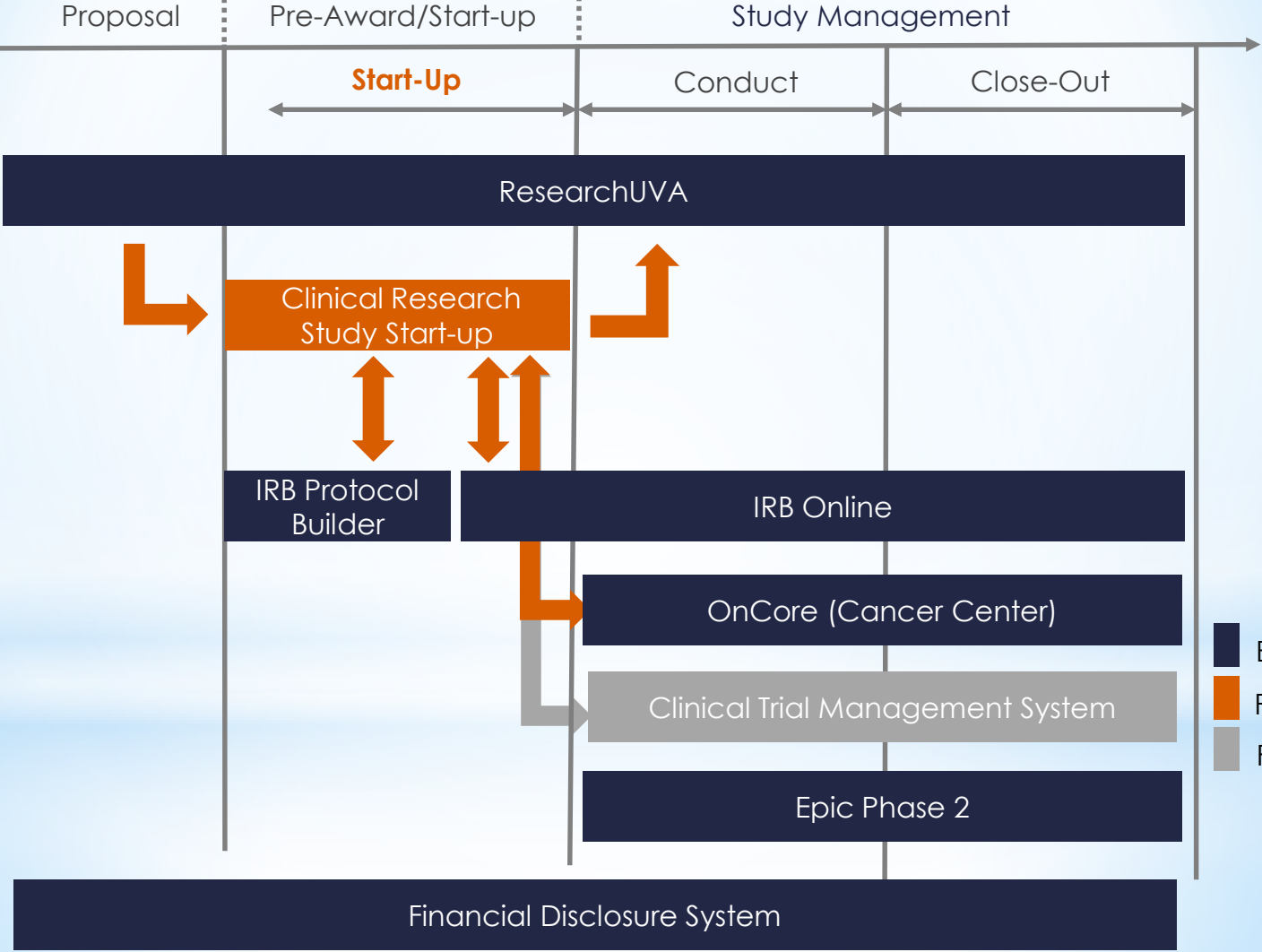


Clinical Research Study Start-Up Steering Committee January 15




Clinical Research Study Start-Up

Process Phases

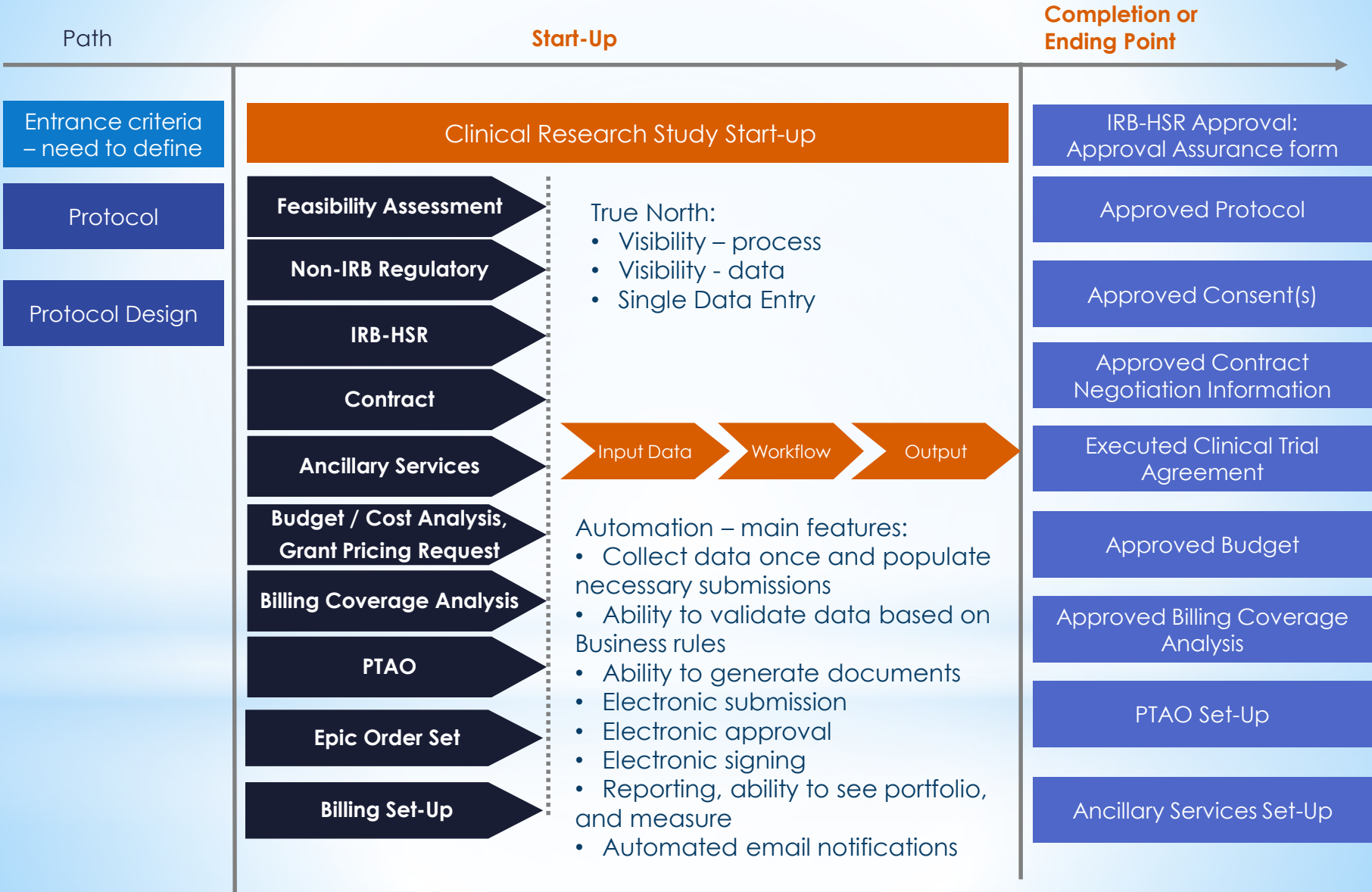


- Existing
- Project Scope
- Future

Scope and assumptions

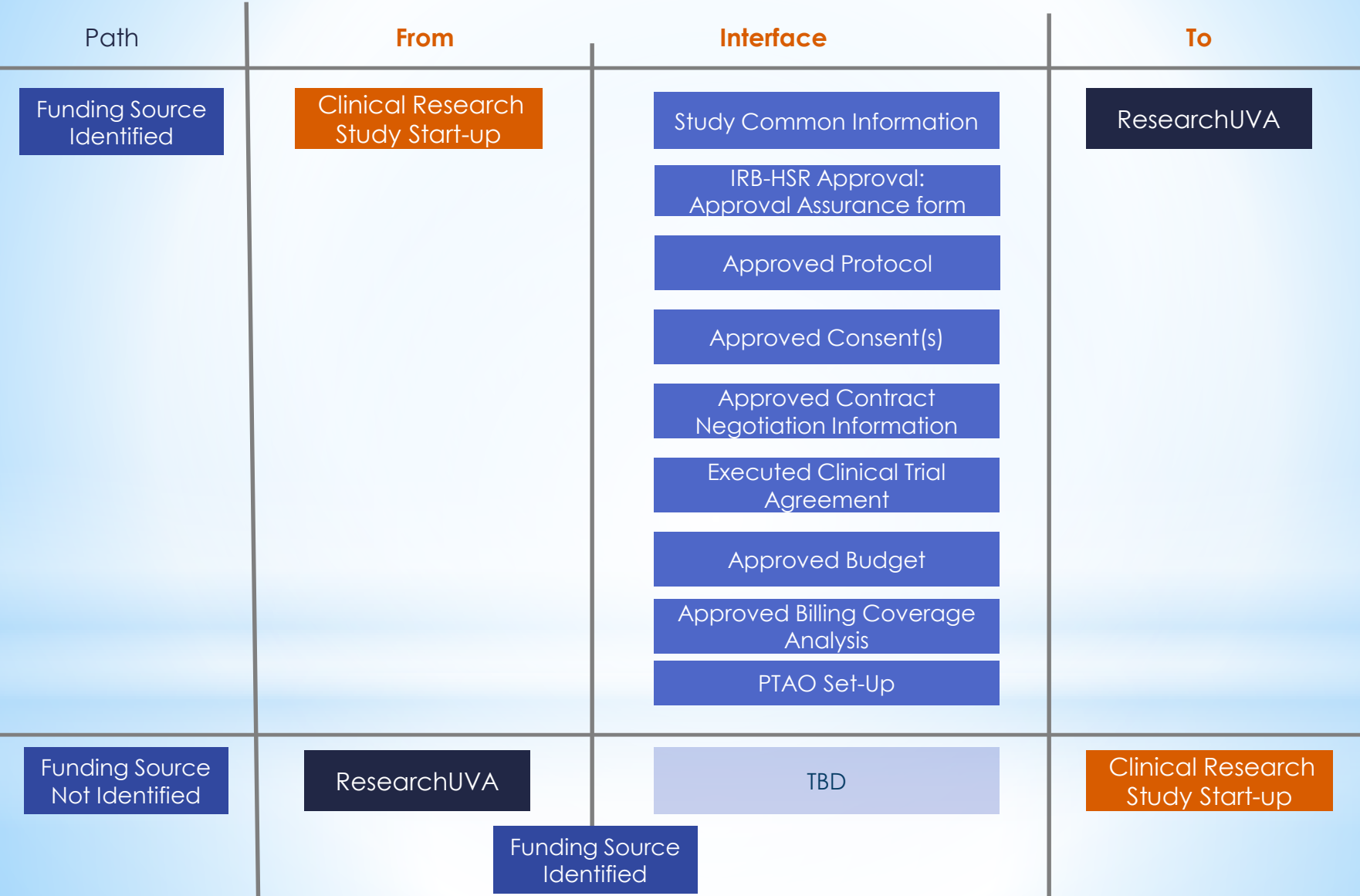
Assumptions or Starting Point	Scope	Start-Up	Completion or Ending Point 
Funding Source Identified	PI initiated	Clinical Research Study Start-up	Ready to Enroll Subjects
Protocol or Protocol Design	Sponsor initiated		IRB-HSR Approval: Approval Assurance form
	Health Science Research at UVA		Approved Protocol
			Approved Consent(s)
			Approved Contract Negotiation Information
			Executed Clinical Trial Agreement
			Approved Budget
			Approved Billing Coverage Analysis
			PTAO Set-Up
			Ancillary Services Set-Up

System capability and functionality



Reduce start-up time to <=100 days, Meet target enrollment goals

Concept of Integration w/ResearchUVA



Funding Source Identified

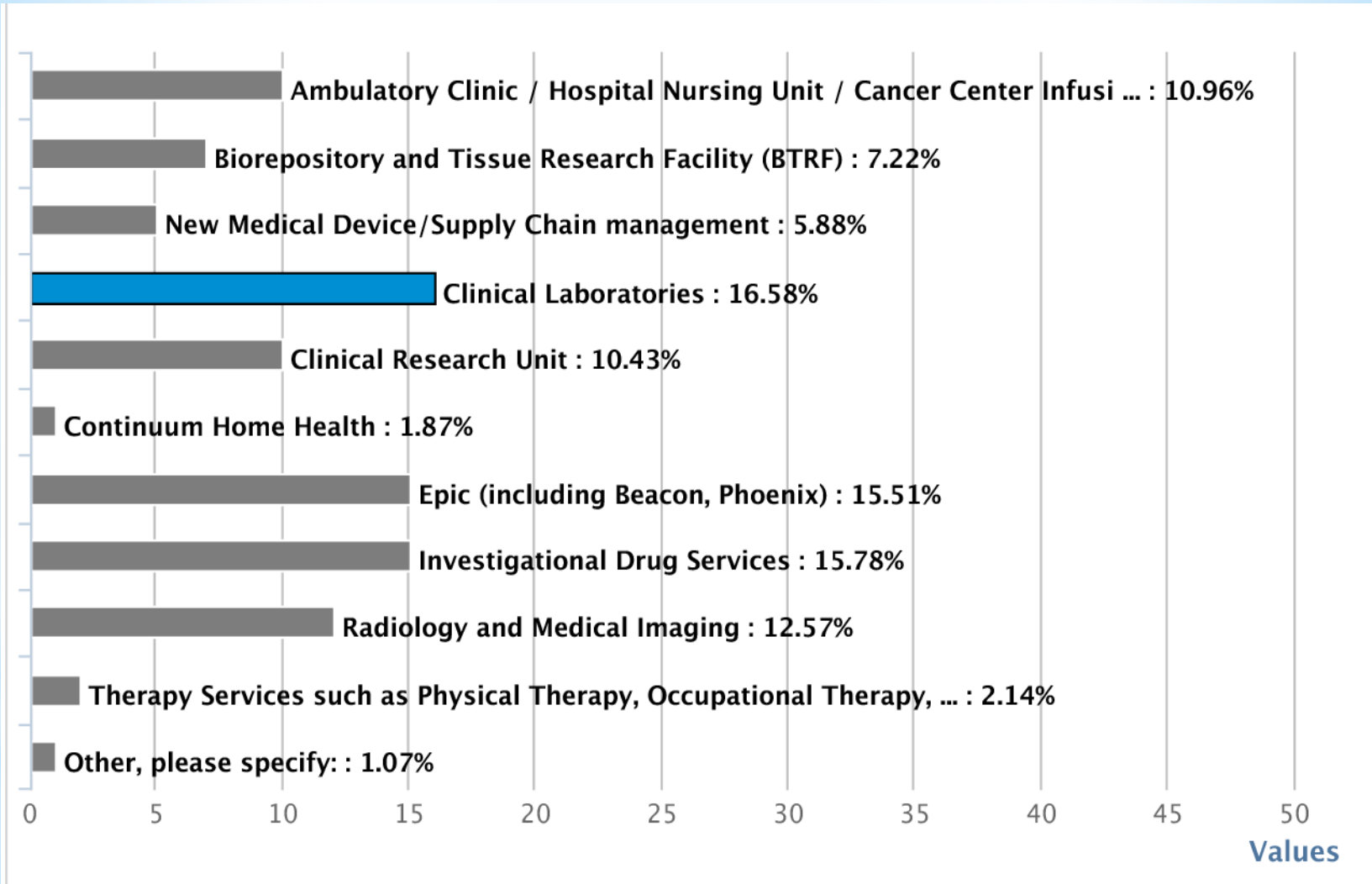
Are we aligned with this approach?

Concept of Integration w/IRB-HSR

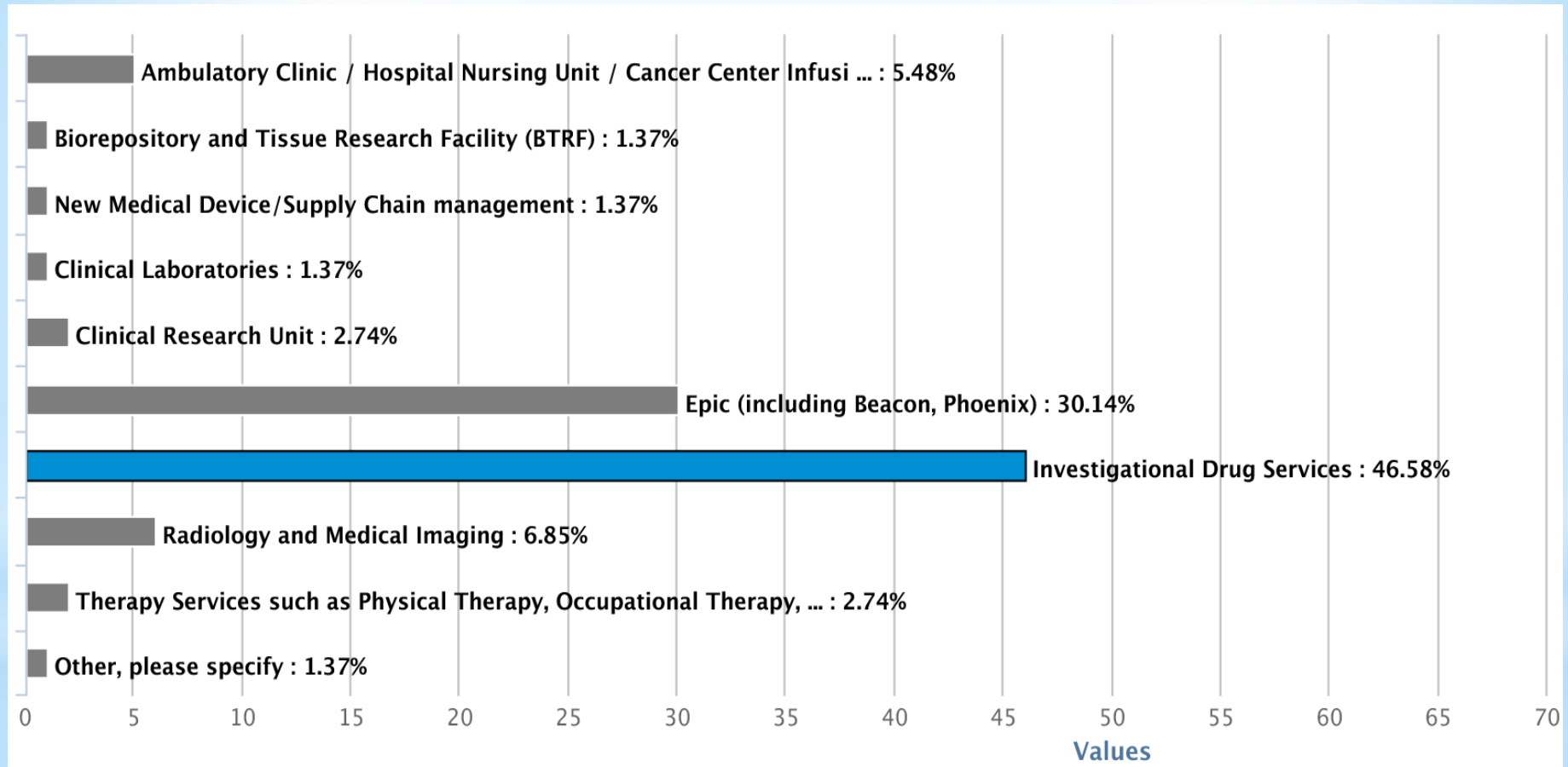
Path	From	Interface	To
	Clinical Research Study Start-up	Study Common Information	IRB Protocol Builder
Protocol	Clinical Research Study Start-up	Non-IRB Regulatory	IRB Protocol Builder
Protocol Design	IRB Protocol Builder	Non-IRB Regulatory	Clinical Research Study Start-up
	IRB Online	IRB-HSR Approval: Approval Assurance form Approved Protocol Approved Consent(s)	Clinical Research Study Start-up

Are we aligned with this approach?

Ancillary Services: Use (May 2015)



Ancillary Services: Priority for Improvement (May 2015)



What is Phase 1 Priority?

Expectations: scope and timeline - TBD

