Electronic Regulatory (eReg) Documentation Overview and System Demonstration

> MUSC Lunch & Learn August 13, 2020





Contents

- Goals
- Timeline
- Features
- Workflow
- Contact







Forte eReg Goals Process improvements and efficiencies

Reduce the administrative burden for regulatory staff

Increase quality assurance and compliance efficiencies



Regulatory workflows for routing/signing documents, delegation of authority, staff training tracking, as well as centralized document storage & linkage with OnCore

Remote monitoring and auditing of records, with audit trails and reporting on key actions

Decrease the cost associated with current regulatory process



Replaces paper binders and associated costs, as well as reduces costs related to on-site monitoring and quality control.



MUSC Goals

Consistent:

• Enterprise-wide, standardized e-Regulatory binder management solution

Efficient:

• Intuitive product that enhances regulatory management and compliance activities

<u>Valid:</u>

• Establish and maintain a 21 CFR Part 11 compliant product

Strategic:

• Phased-in Go Live plan, considering OnCore release and interface

<u>Guided</u>:

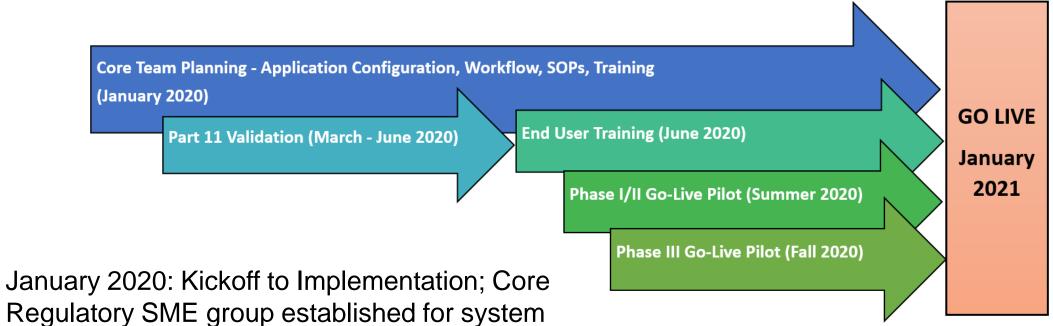
• Robust user training, resources and ongoing support



eReg: Timeline



MUSC eReg Implementation Timeline & Milestones



- Regulatory SME group established for system design, recommendations and SOPs
- May 2020: 21 CFR Part 11 Validation completed; SME group recommendations solidified

June 2020: Product available for small group pilots; training and SOPs development underway





eReg: Features



Key Features

- 21 CFR Part 11 Compliant product
- Centralized electronic, regulatory document storage
- Manage organization and staff credentials that flow onto studies
- Workflow for routing/signing documents
 - Protocol Documents
 - Delegation of authority maintenance
 - Staff training tracking
- Remote compliance reviews (monitoring, auditing)
- Management reports for system access and tracking



eReg Protocol Binder

eREG. Menu = Roles Protoc	cols Contacts Reference L	Lists Organizations Regulatory Templates Rev	view Sessions Sign Do	ocuments Reports	Test 🔒	
Protocols > Lart Review Study						
Overview	Protocol: C	Chart Review Study				Actions -
Summary		-				
Details	Overview					
Organizations	0.001.000					
Staff		Title Update on title name				
Staff Training		ICT Number				
Delegation of Authority		Study Site				
Delegation of Authority Log		-				
Informed Consent Documentation		Investigator				
IRB Approvals and Correspondence	Next Review S	ession Date				
Protocol		Staff Training Cignature Statuses		Delegation of Authority		
Protocol Deviation Form or Memo		Staff Training Signature Statuses		Delegation of Authority		
Screening/Enrollment Log		Past Signature Due Date	0	Staff Members Need to Sign Tasks	1	
Serious Adverse Events		Routed But Not Due Yet	0	Staff Members Need PI Signoff on Tasks	2	
(SAE)/Unanticipated Problem Documents				Staff Members Need PI Signoff on Stop Dates	0	
Sponsor Correspondence						
Study Communication						
Case Report Forms/Source Documents						
Other Documents	Cox.	Expiring Protocol Documents		Protocol Document Signature Statuses		Cox



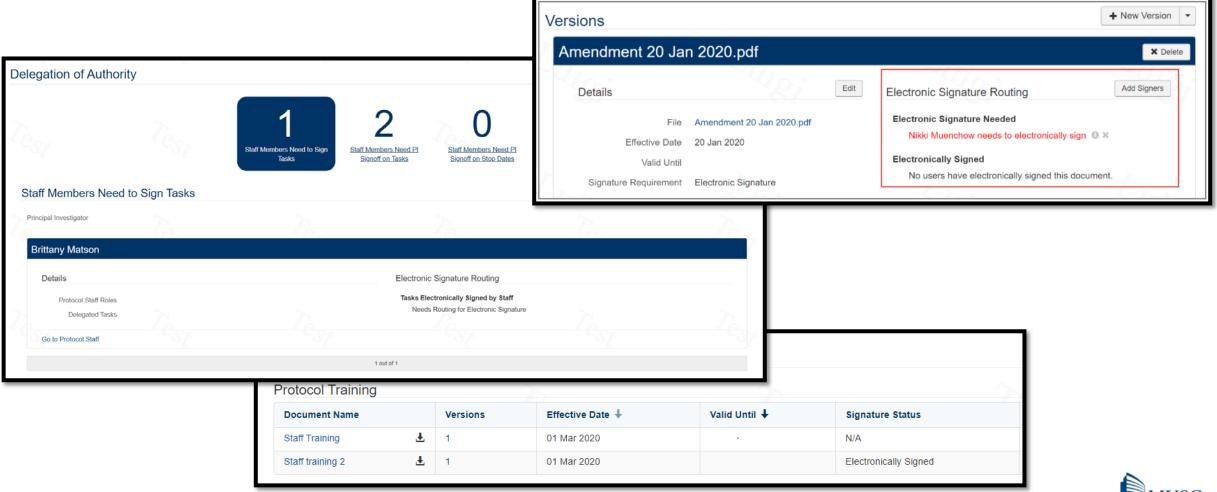
Manage protocol staff and organization credentials

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S	First Name 🕇	Last Name 🕇	Start Date	Stop Date	Protocol Staff Roles	Credential Status
	Nikki	Muenchow	16 <mark>J</mark> an 2020		Clinical Trial Coordinator	Complete
	Penelope	Pettigrew	20 Jan 2020		Clinical Research Associate	Incomplete
	Benjamin	Smith	20 Jan 2020		Affiliate Principal Investigator	Incomplete

Organization 🕇	IRB?	Laboratory?	Start Date	Stop Date	Documentation Stat
MUSC Office of Research Integrity IRB	Yes	No	01 Jul 2019	•	Complete



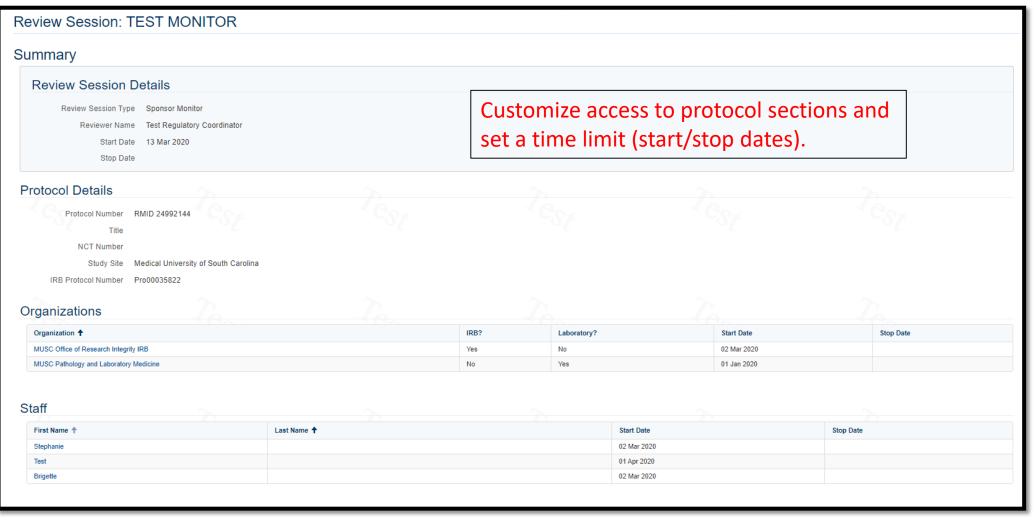
Route and sign and track protocol documents, DOA and training records







Remote monitoring/auditing sessions







Reports

Downloaded, excel file Standard Reports are available to manager and PI users in a 'Reports' section.

Name 🕇	Description	Report Group	Туре
Contact Integration Discrepancies	Displays instances where contact records could not be linked or updated via Hub integration. Only contacts that you have permission to view appear in the report.	Hub Integration	Standard
Delegation of Authority Log	This is the released Delegation of Authority Log report. You can only report on protocols for which you have permission to view staff information. If this report is run for a multi-site protocol, only documents from the coordinating center are included.	Delegation of Authority and Signature Log Reports	Standard
Document Upload Details	Displays the protocol documents, staff training documents, contact credentials, and regulatory documents uploaded into the system during a specified time range. Only documents that you have permission to view appear in the report. If this report is run for a multi-site protocol, only documents from the coordinating center are included.	Standard Reports	Standard
Electronic Signature Notification Tracking	Displays the electronic signature notifications the system attempted to send to a specific user.	Standard Reports	Standard
Electronic Signature Status for Credentials	Displays the electronic signature status of contact credentials for a specific contact.	Standard Reports	Standard
Electronic Signature Status for Protocol Documents	Displays the electronic signature status for protocol documents for a specified protocol. If this report is run for a multi-site protocol, only documents from the coordinating center are included.	Standard Reports	Standard
Expiring Organization Documents	Displays the documents associated with the selected organizations that will expire in the specified timeframe. If you don't specify any organizations, all organizations to which you have access are reported on. Only expiring documents and credentials that you have permission to view appear in the report.	Standard Reports	Standard
Expiring Protocol Documents	Displays the documents associated with selected protocols that will expire in the specified timeframe. If you don't specify any protocols, all protocols to which you have access are reported on. Only expiring documents that you have permission to view appear in the report. If this report is run for a multi-site protocol, only documents from the coordinating center are included.	Standard Reports	Standard
Organization Integration Discrepancies	Displays instances where organization records could not be linked or updated via Hub integration. Only organizations that you have permission to view appear in the report.	Hub Integration	Standard
Protocol Document Audit	Displays information about the protocol documents that were added, edited, and deleted for a specified protocol. The report includes only documents that were uploaded into eReg and not URLs. If this report is run for a multi-site protocol, only documents from the coordinating center are included.	Standard Reports	Standard
Protocol Integration Discrepancies	Displays instances where protocol and protocol staff records could not be updated via Hub integration. Only protocols and protocol staff that you have permission to view appear in the report.	Hub Integration	Standard
Staff Training Tracker	Displays the signature status for a specified protocol's staff training documents. If this report is run for a multi-site protocol, only documents from the coordinating center are included.	Standard Reports	Standard





Features available at a later date

- Multi-site protocol regulatory document storage
- Protocol/Staff Importing from OnCore



Features not supported in the product

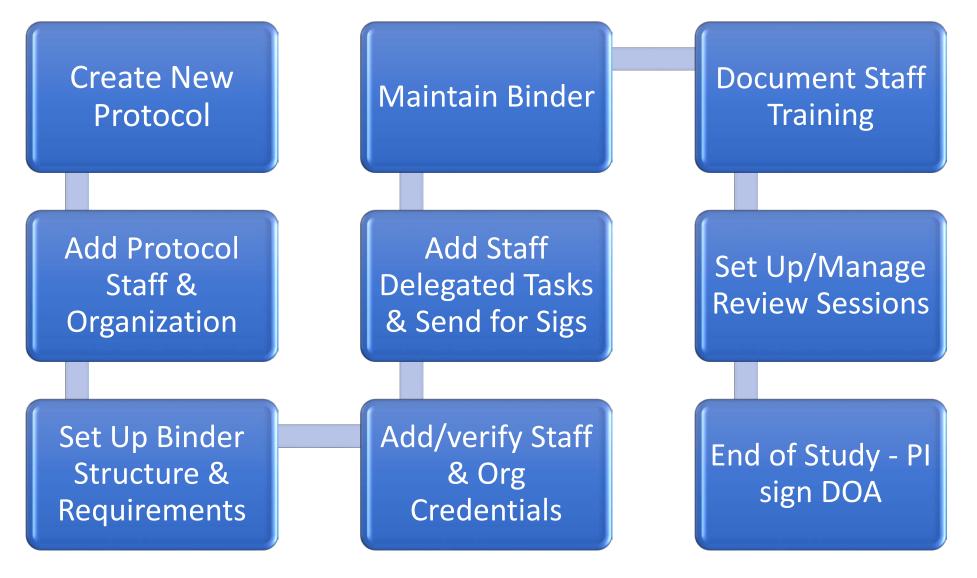
- Data Migration of existing study data
- Integration with eIRB
- External Document Signatures







Workflow







Electronic Regulatory (eReg)

Questions?

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