

ADOPTing Rave

Quality Control for Protocol Materials

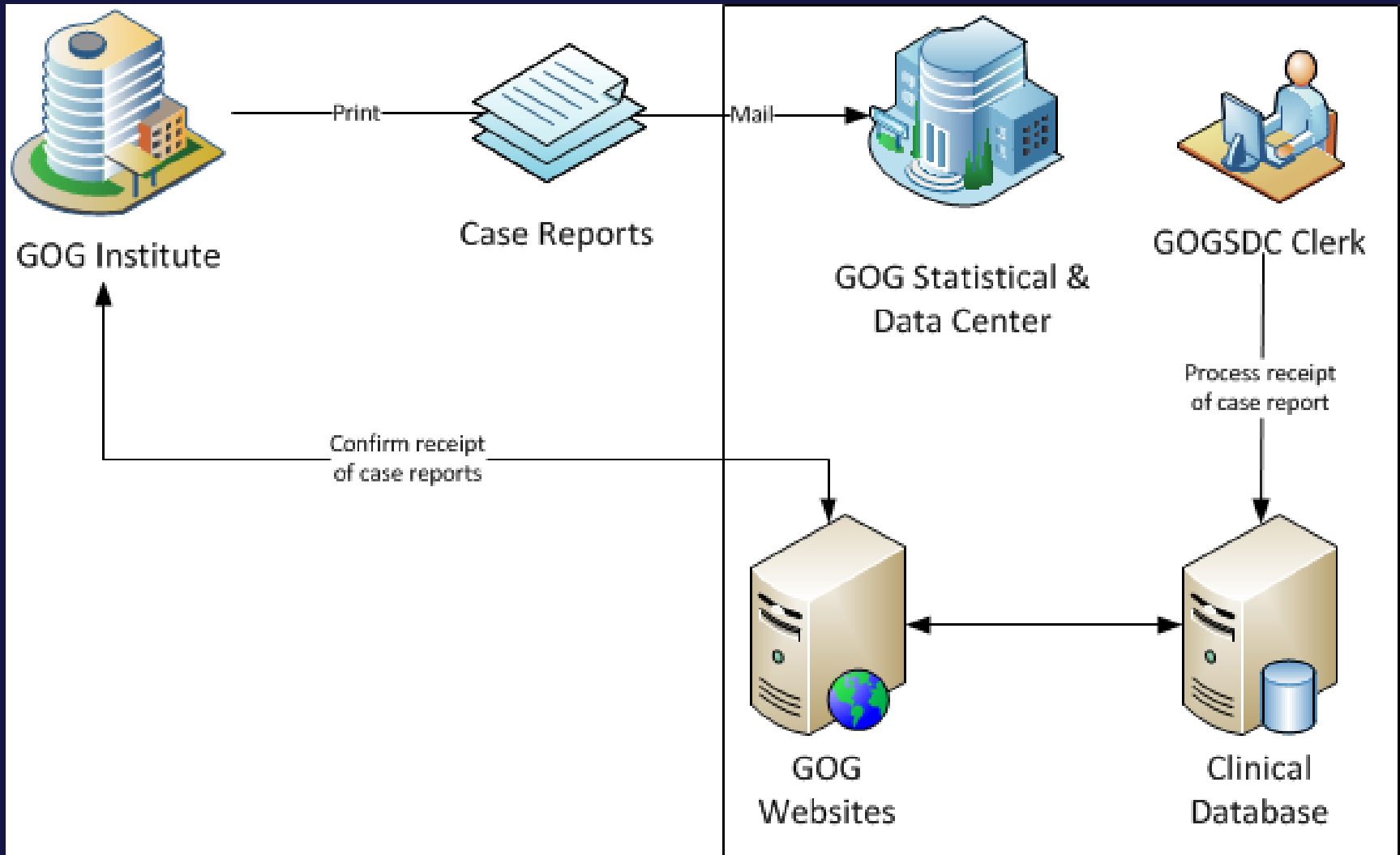
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Buffalo, New York

OUTLINE

1. Background
 - I. Existing Process
 - II. Case Report uses at GOG
2. Rave
 - I. Quick Overview
 - II. Implementations
 - I. Multiple forms
 - II. Consolidated form
 - III. Implementation review
3. Conclusion
4. Looking forward
5. Questions?

BACKGROUND

Existing GOG Process



BACKGROUND

Existing GO



GOG Institute

Report Uploader

GOG #: 083-0229-072-N

Pat. Initials: P H

Report type: PATH REPORT PRIMARY SURGERY

PDF file:

Browse...

upload

Report Uploader

GOG #: 083-0229-072-N

Pat. Initials: P H

Report type: PATH REPORT PRIMARY SURGERY

PDF file:

Browse...

upload

Upload Timestamp: 5/3/2013 8:29:02 AM

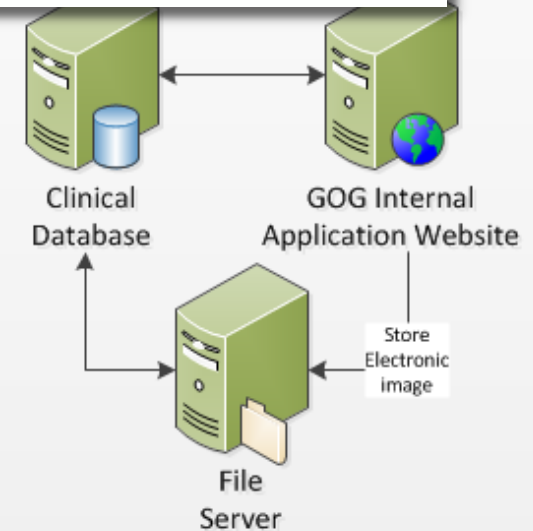
Uploaded From: [gog_path_surgery_report_ph.pdf](#)

Form PR1 for patient 083-0229N-072 has been uploaded successfully.

Please click below to return

[Patient Form Schedule](#)

View File

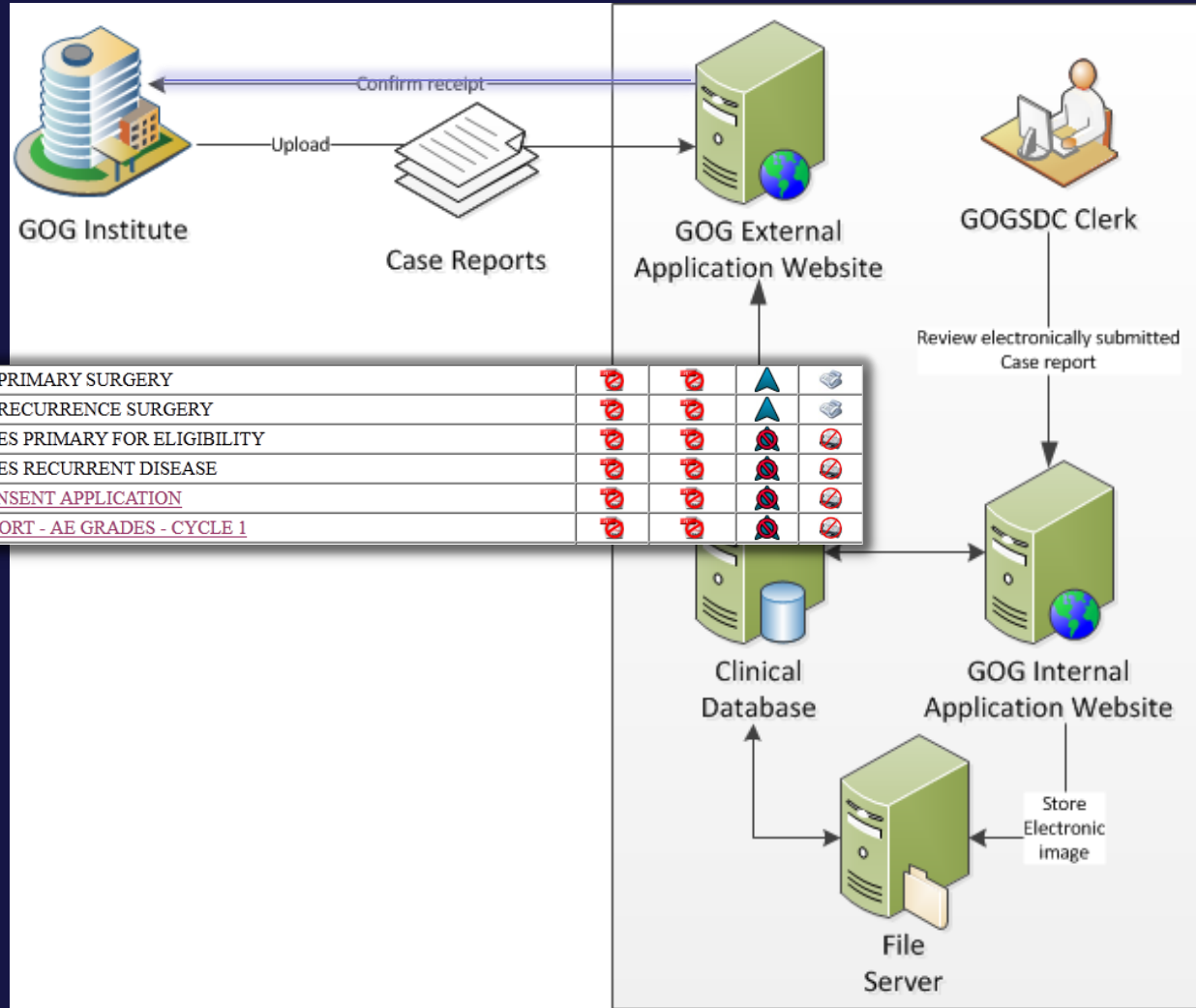


BACKGROUND

EXISTING GOG PROCESS

Current Status

12/3/2012	Pending Approval	PR1	PATH REPORT PRIMARY SURGERY				
12/3/2012	11/16/2012	PRR	PATH REPORT RECURRENCE SURGERY				
12/3/2012	12/6/2012	S-1	STAINED SLIDES PRIMARY FOR ELIGIBILITY				
12/3/2012	12/6/2012	S-R	STAINED SLIDES RECURRENT DISEASE				
12/3/2012	12/6/2012	SCA	SPECIMEN CONSENT APPLICATION				
12/3/2012	11/28/2012	TOX_AE_GRD_001	TOXICITY REPORT - AE GRADES - CYCLE 1				



BACKGROUND

Existing GOG Process

Approve Deny

GOG # 083-0229N-072
Form Type: PR1
Submitted By: jkillion
Date Uploaded: 4/12/2013

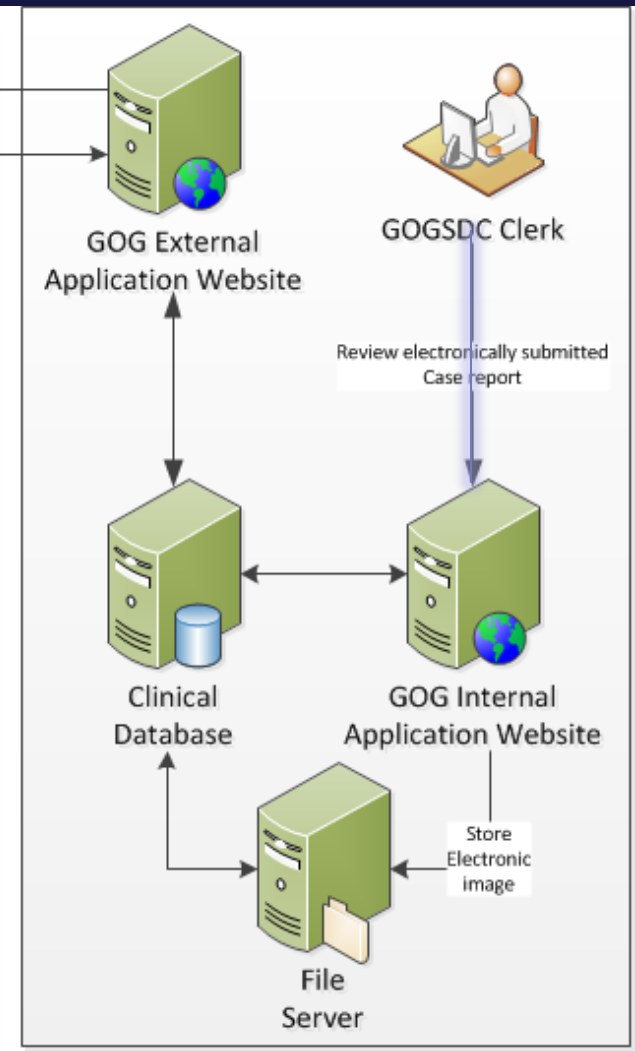
Pending
Instcode:
Protocol:
Form Type:

Filter Clear

[083-0229N-072_Form-PR1](#)
[046-0263-003_Form-PR-B](#)
[073-0235-046_Form-DS](#)
[073-0235-046_Form-OP](#)
[073-0235-046_Form-PR](#)
[073-0235-046_Form-CR](#)
[094-0186H-014_Form-BDR](#)
[074-0235-046_Form-DS](#)
[094-0186H-014_Form-PR1](#)
[074-0235-045_Form-DS](#)
[074-0235-045_Form-OP](#)
[064-0186H-002_Form-BDR](#)
[021-0258-018_Form-DS](#)
[021-0258-018_Form-OP](#)
[083-0244-041_Form-OP](#)
[134-3003-001_Form-PR1](#)
[066-0186I-007_Form-BDR](#)

Form Image

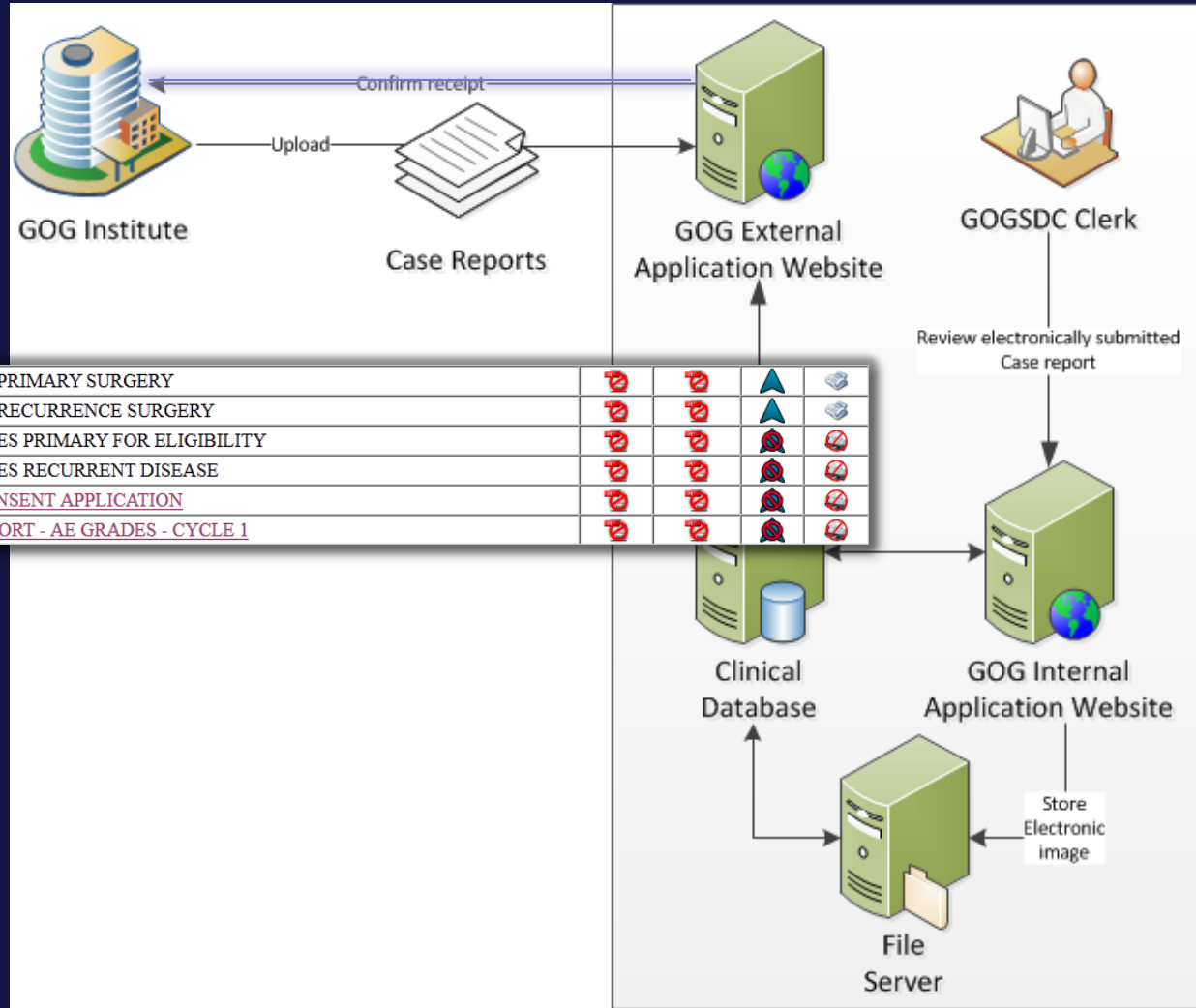
Form Image



BACKGROUND

Existing GOG Process

Date received



12/3/2012	11/16/2012	PR1	PATH REPORT PRIMARY SURGERY	🚫	🚫	📶	📁
12/3/2012	11/16/2012	PRR	PATH REPORT RECURRENCE SURGERY	🚫	🚫	📶	📁
12/3/2012	12/6/2012	S-1	STAINED SLIDES PRIMARY FOR ELIGIBILITY	🚫	🚫	🚫	🚫
12/3/2012	12/6/2012	S-R	STAINED SLIDES RECURRENT DISEASE	🚫	🚫	🚫	🚫
12/3/2012	12/6/2012	SCA	<u>SPECIMEN CONSENT APPLICATION</u>	🚫	🚫	🚫	🚫
12/3/2012	11/28/2012	TOX_AE_GRD_001	<u>TOXICITY REPORT - AE GRADES - CYCLE 1</u>	🚫	🚫	🚫	🚫

BACKGROUND

Existing GOG Process

- **Current GOG process has been in place for nearly 6 years**
 - Average around 38 forms a day
 - Over 19,000 patients for 120 protocols
 - Over 76,000 case reports and amendments
- **Allows data coordinators to better focus on data quality**

BACKGROUND

Case Report uses at GOG

1. Clinical Data validation
2. Study Chair reviews
3. Modality reviews
4. Maintaining shadow charts
5. Site audits
6. SAE reviews

RAVE

Quick Overview

Web-based Electronic Data Capture (EDC) system

The screenshot displays the RAVE Subject Overview page for subject 000-XXXX-022. The interface includes a navigation menu on the left, a central table of visits, and a task summary on the right.

Navigation Menu:

- 000-XXXX-022
- Enrollment Forms
- Baseline
- Visit 01
- Patient Administration
- CRF History
 - 000-XXXX-022 - Visit Information - Baseline
 - 000-XXXX-022 - Step Information
 - 000-XXXX-022 - Demography
 - 000-XXXX-022 - Visit Information

Subject Enrollment Table:

Visit	Date
Baseline	21 May 2013
Visit 01	11 Jun 2013

Task Summary: Subject

Task	Pages
Requiring Signature	0
NonConformant Data	0
Open Queries	0
Answered Queries	0
Requiring Review	0
Requiring Verification	0
Overdue Data	0
Ready for Data Lock	5
Cancel Queries	0

Page Information: CRF Version 125 - Page Generated: 16 May 2013 14:51:31 Eastern Daylight Time

Rave Subject Overview

RAVE

Quick Overview

Web-based Electronic Data Capture (EDC) system

The screenshot displays the RAVE EDC system interface. On the left is a sidebar menu for subject 000-XXXX-022, including options for Enrollment Forms, Baseline, SEDES Submissions, Visit 01, and Patient Administration. Below the menu is an 'Information' section with links for Demography and Visit Information. The main content area features a header with 'SF', 'GOG Stat & Data Center', and the subject ID. A table shows data points with dates: 21 May 2013 and 11 Jun 2013. To the right is a 'Task Summary: Subject' section with a list of tasks and their page counts. At the bottom left, there is an 'Icon Key' and a footer indicating 'CRF Version 125 - Page Generated: 16 May 2013 14:51:31 Eastern Daylight Time'.

000-XXXX-022

Enrollment Forms

Baseline

SEDES Submissions

Visit 01

Patient Administration

Information

000-XXXX-022 - Demography

000-XXXX-022 - Visit Information

Icon Key

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SF GOG Stat & Data Center 000-XXXX-022

	Date
	21 May 2013
	11 Jun 2013

Grid View
Subject Administration
Subject Sharing

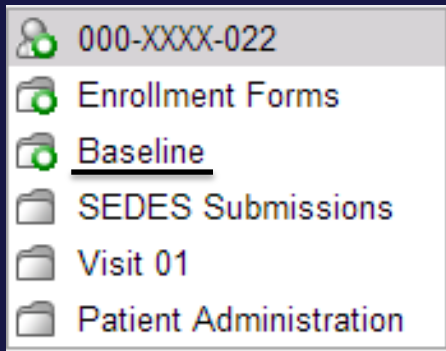
Task Summary: Subject

	Pages
▶ Requiring Signature	0
▶ NonConformant Data	0
▶ Open Queries	0
▶ Answered Queries	0
▶ Requiring Review	0
▶ Requiring Verification	0
▶ Overdue Data	0
▶ Ready for Data Lock	5
▶ Cancel Queries	0

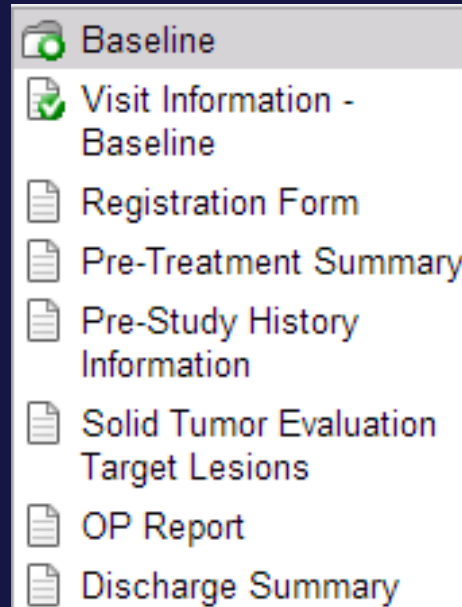
RAVE

Quick Overview

Web-based Electronic Data Capture (EDC) system



Folders



Forms

RAVE

Quick Overview

Web-based Electronic Data Capture (EDC) system

The screenshot displays the RAVE EDC system interface for a patient with ID 000-XXXX-022. The interface is divided into several sections:

- Navigation Menu (Left):** A list of folders for the patient's data, including Enrollment Forms, Baseline, SEDES Submissions, Visit 01, and Patient Administration.
- Form Navigation (Center):** A list of forms available for the patient, including Baseline, Visit Information - Baseline, Registration Form, Pre-Treatment Summary, Pre-Study History Information (highlighted), Solid Tumor Evaluation Target Lesions, OP Report, and Discharge Summary.
- Data Entry Form (Right):** A form with various input fields and radio buttons. The form includes questions such as "Prior immunological therapy?", "Non-Protocol Biologic Response Modifier?", "Prior Radiation Therapy", and "Is the site of recurrence within the field previously treated by radiation therapy?". Each question has a "No" or "Yes" radio button and a text input field.
- Comments Section (Bottom):** A section for entering comments, with a text input field and a "Comments" label.

Form & Datapoints

RAVE

Quick Overview

Web-based Electronic Data Capture (EDC) system

Subject: 000-XXXX-022
Page: Pre-Study History Information - Baseline

ON STUDY HISTORY INFORMATION

[Disease Description](#)

Date of Definitive Histologic Diagnosis of Primary Tumor **Date field** ...

Stage at Diagnosis (FIGO) **Drop down list** ...

Non-Chemotherapy Treatment

Prior Hormonal Therapy No Yes

Prior immunological therapy? No Yes

Non-Protocol Biologic Response Modifier? No Yes

Prior Radiation Therapy No Yes

Is the site of recurrence within the field previously treated by radiation therapy? **Radio buttons** Yes No

Comments

Comments **Text area**

Form & Datapoints

RAVE

Quick Overview

FileUpload control

Subject: 000-XXXX-022
Page: Discharge Summary - Baseline

DISCHARGE SUMMARY

Discharge Summary PDF image [0229N Rave Updates Apr 2013.pdf](#)

[Printable Version](#) [View PDF](#) [Icon Key](#)

CRF Version 125 - Page Generated: 16 May 2013 15:30:40 Eastern Daylight Time

Save Cancel

File Name	Date/Time	File Type
Form-BP_INFO_002_20130225150040	3/6/2013 4:35 PM	Adobe Ac
Form-BP_INFO_002_20130225150040	2/25/2013 3:00 PM	TIFF imag
Form-BP_INFO_003_20130225150036	3/6/2013 4:35 PM	Adobe Ac
Form-BP_INFO_003_20130225150036	2/25/2013 3:00 PM	TIFF imag
Form-BP_INFO_004_20130215160053	3/6/2013 4:35 PM	Adobe Ac
Form-BP_INFO_004_20130215160053	2/15/2013 4:00 PM	TIFF imag
Form-BP_INFO_005_20130305154935	3/6/2013 4:35 PM	Adobe Ac
Form-BP_INFO_005_20130305154935	3/5/2013 3:49 PM	TIFF imag
Form-BP_INFO_006_20130315130524	3/15/2013 1:05 PM	TIFF imag
Form-CY_DI_001_20130225152906	3/6/2013 4:35 PM	Adobe Ac
Form-CY_DI_001_20130225152906	2/25/2013 3:29 PM	TIFF imag
Form-CY_DI_002_20130225152954	2/6/2013 4:35 PM	Adobe Ac

RAVE

Quick Overview

Obtaining uploaded Case Reports from Rave

Subject: 000-XXXX-022
Page: Discharge Summary - Baseline

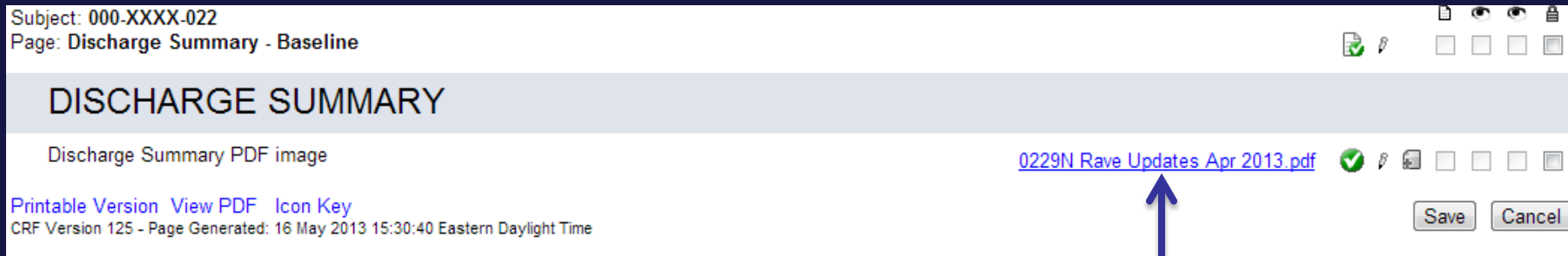
DISCHARGE SUMMARY

Discharge Summary PDF image

[0229N Rave Updates Apr 2013.pdf](#)

Printable Version View PDF Icon Key
CRF Version 125 - Page Generated: 16 May 2013 15:30:40 Eastern Daylight Time

Save Cancel



Click link to download file

RAVE

First Implementation

One case report per Rave form

Subject: 000-XXXX-022
Page: Discharge Summary - Baseline

DISCHARGE SUMMARY

Discharge Summary PDF image No file chosen

[Printable Version](#) [View PDF](#) [Icon Key](#)

CRF Version 125 - Page Generated: 15 May 2013 15:54:10 Eastern Daylight Time

Subject: 000-XXXX-022
Page: OP Report - Baseline

OPERATIVE REPORT

Date of operative procedure ...

Operative Report PDF image No file chosen

[Printable Version](#) [View PDF](#) [Icon Key](#)

CRF Version 125 - Page Generated: 15 May 2013 15:55:12 Eastern Daylight Time

Subject: 000-XXXX-022
Page: Path Report - Primary Surgery - Visit 01

PATH REPORT - PRIMARY SURGERY

Date of primary surgery ...

Path Report - Primary Surgery PDF image No file chosen

[Printable Version](#) [View PDF](#) [Icon Key](#)

CRF Version 125 - Page Generated: 15 May 2013 15:56:20 Eastern Daylight Time

RAVE

First Implementation

Leverage Rave calendar functionality

[Home](#) | [LPO2NCL_SF](#) | [GOG Stat & Data Center](#) | [000-XXXX-022](#)

[000-XXXX-022](#)
[Enrollment Forms](#)
[Baseline](#)
[Visit 01](#)
[Patient Administration](#)

[Subject Enrollment](#)

[Grid View](#)
[Subject Administration](#)
[Subject Sharing](#)

Visit	Date
Baseline	21 May 2013
Visit 01	11 Jun 2013

Task Summary: Subject

	Pages
Requiring Signature	0
NonConformant Data	0
Open Queries	0
Answered Queries	0
Requiring Review	0
Requiring Verification	0
Overdue Data	0
Ready for Data Lock	5
Cancel Queries	0

[Icon Key](#)

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Subject: 000-XXXX-022
 Page: Path Report - Primary Surgery - Visit 01

PATH REPORT - PRIMARY SURGERY

Date of primary surgery

Path Report - Primary Surgery PDF image No file chosen

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CRF Version 125 - Page Generated: 15 May 2013 15:56:20 Eastern Daylight Time

RAVE

First Implementation

Capture additional data with case report file

Subject: 000-XXXX-022
Page: OP Report - Baseline

OPERATIVE REPORT

Date of operative procedure **Abstracted data** ...

Operative Report PDF image No file chosen

[Printable Version](#) [View PDF](#) [Icon Key](#)

CRF Version 125 - Page Generated: 15 May 2013 15:55:12 Eastern Daylight Time

Subject: 000-XXXX-022
Page: Path Report - Primary Surgery - Visit 01

PATH REPORT - PRIMARY SURGERY

Date of primary surgery **Abstracted data** ...

Path Report - Primary Surgery PDF image No file chosen

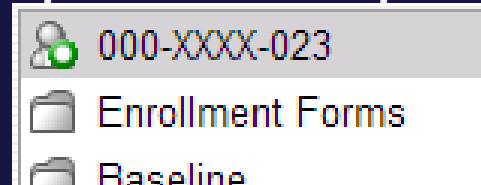
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RAVE

Second Implementation

Capture all patient case reports on one form



Subject: 000-XXXX-023
Page: Case Report File Uploads

#	Case Report	PDF image	Due Date	
1	Operative Report	<input type="button" value="Choose File"/> No file chosen	21 MAY 2013	<input type="radio"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
2	Discharge Summary	<input type="button" value="Choose File"/> No file chosen	21 MAY 2013	<input type="radio"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
3	Path Report - Primary Surgery	<input type="button" value="Choose File"/> No file chosen	11 JUN 2013	<input type="radio"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

Add a new Log line Inactivate

[Printable Version](#) [View PDF](#) [Icon Key](#)

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RAVE

Second Implementation

Capture all patient case reports on one form

Pre-loaded per study requirements

Calculated and pre-loaded per patient

Subject: 000-XXXX-023
Page: Case Report File Uploads

#	Case Report	PDF image	Due Date	
1	Operative Report	<input type="button" value="Choose File"/> No file chosen	21 MAY 2013	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
2	Discharge Summary	<input type="button" value="Choose File"/> No file chosen	21 MAY 2013	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
3	Path Report - Primary Surgery	<input type="button" value="Choose File"/> No file chosen	11 JUN 2013	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

Add a new Log line Inactivate

[Printable Version](#) [View PDF](#) [Icon Key](#)

CRF Version 127 - Page Generated: 15 May 2013 16:06:29 Eastern Daylight Time

RAVE

Second Implementation

Capture all patient case reports on one form

Subject: 000-XXXX-023
Page: Case Report File Uploads

#	Case Report	PDF image	Due Date	
1	OPERATIVE REPORT	Form-F-1_20121025114320.1.pdf	21 MAY 2013	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
2	DISCHARGE SUMMARY	Form-F-R_20121025115005.1.pdf	21 MAY 2013	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
3	PATH REPORT - PRIMARY SURGERY	Form-PR1_20130515142923.amd1.pdf	11 JUN 2013	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

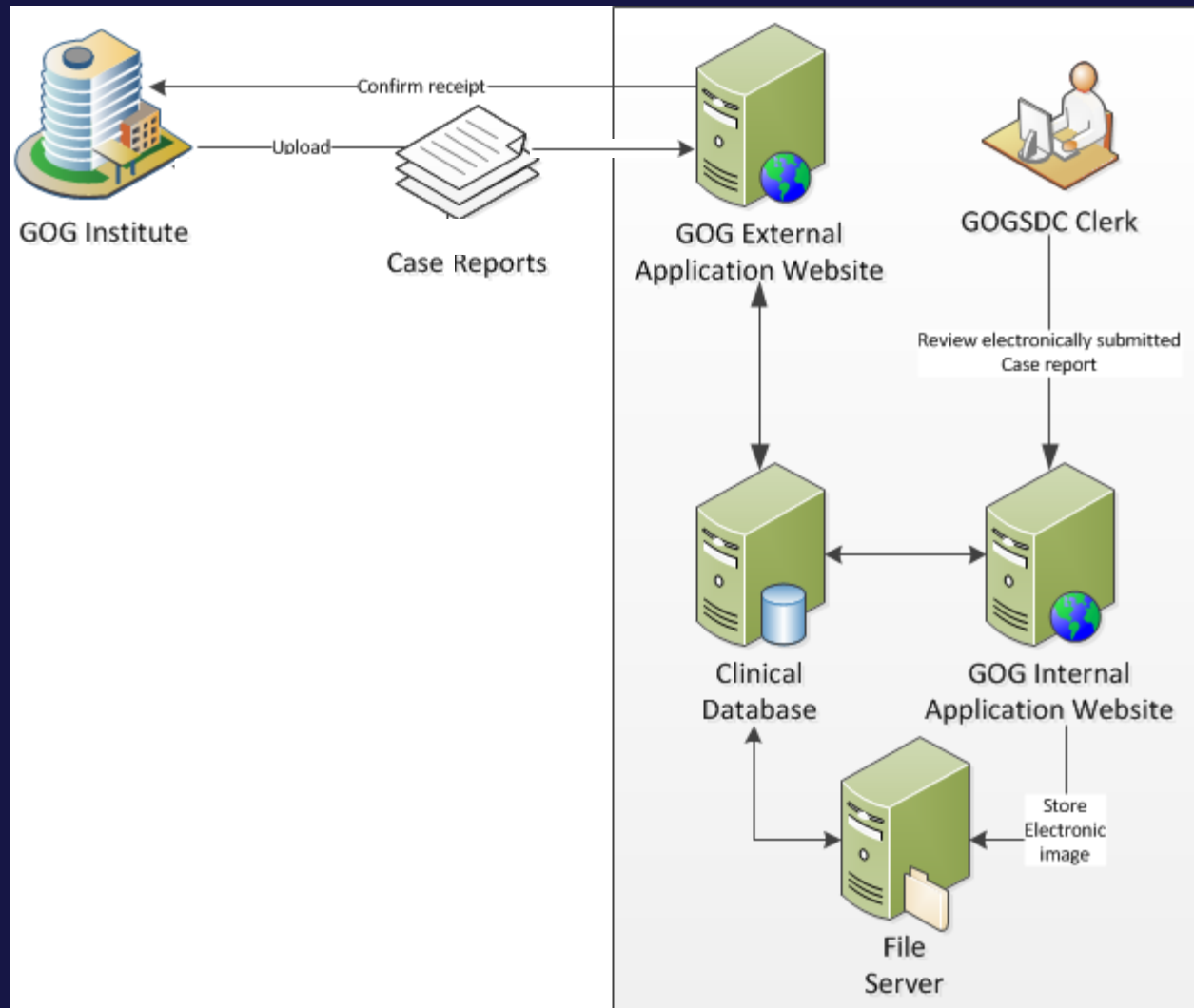
Add a new Log line Inactivate

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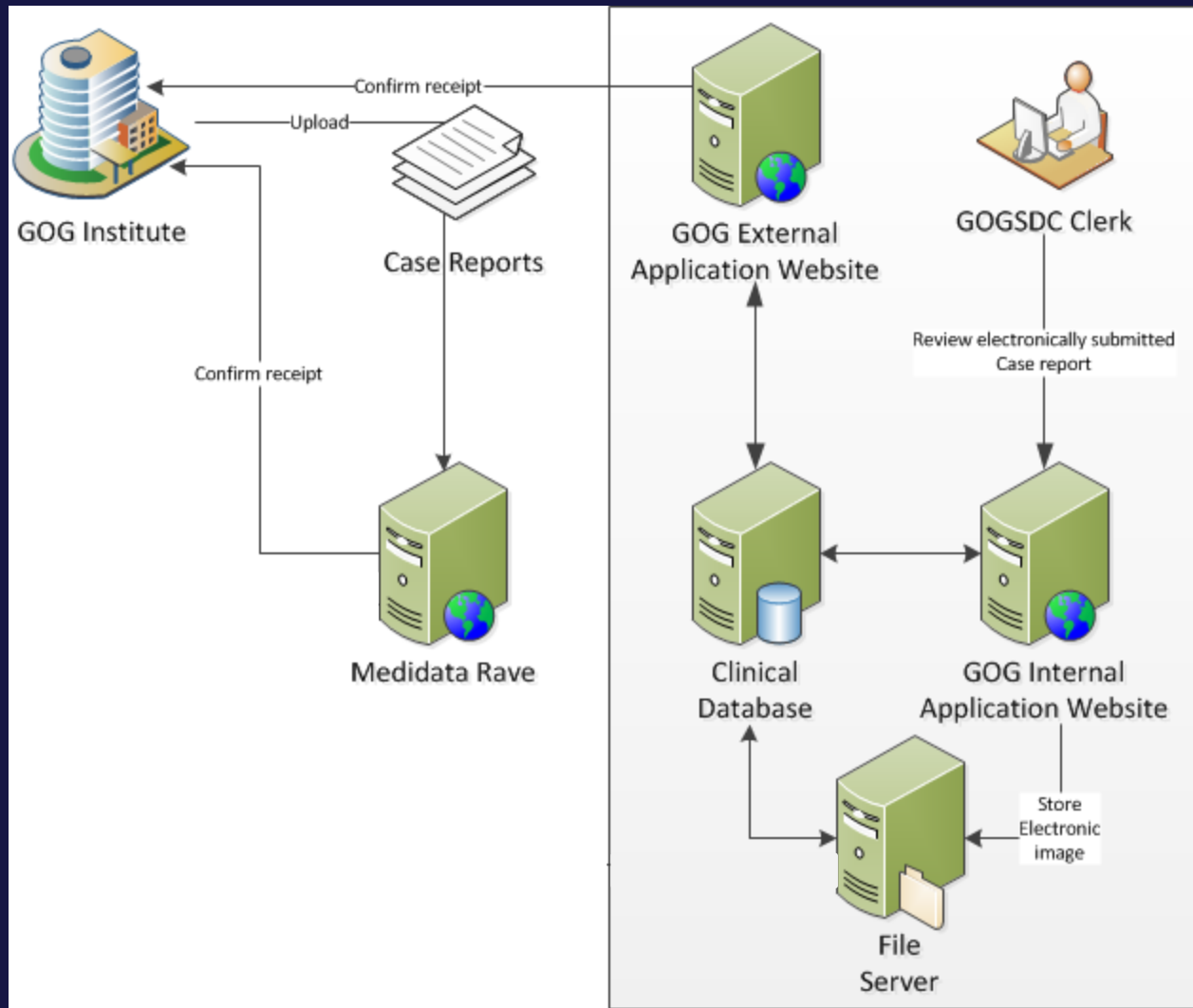
RAVE

Implementation Review



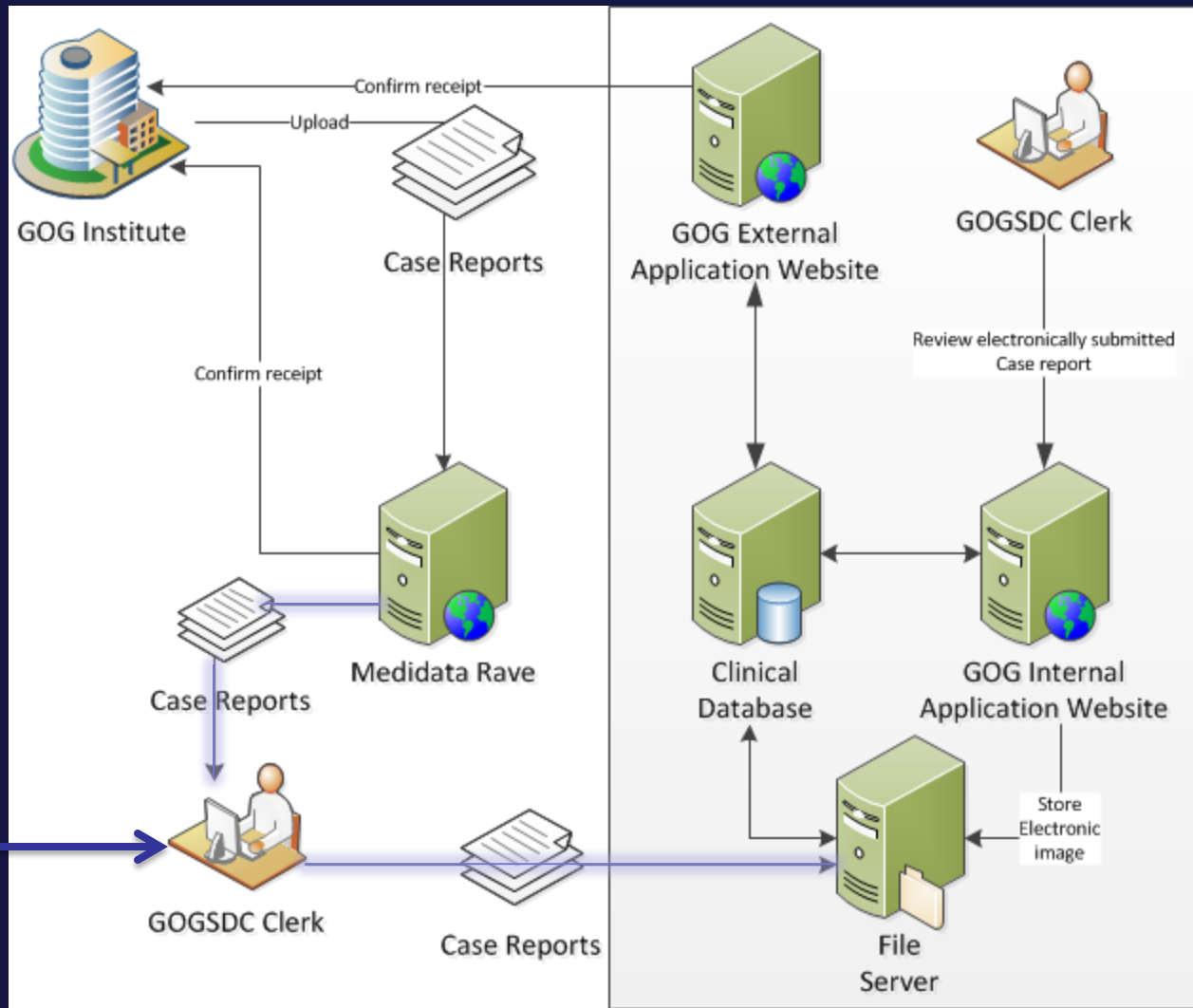
RAVE

Implementation Review



RAVE

Implementation Review



New manual process introduced
Not ideal

RAVE

Implementation Review

Implementation	Advantages	Drawbacks
One per form	<ul style="list-style-type: none">• Leverage Rave Calendaring• Collect additional data with case report• Easy to understand for site users	<ul style="list-style-type: none">• Retrieving case reports is tedious• Monitoring submission of amended case reports is difficult
Consolidated	<ul style="list-style-type: none">• Improved monitoring and retrieval for Clinical Data Coordinator• Easier to add additional desired case reports	<ul style="list-style-type: none">• Loss of Rave Calendaring functionality• Collecting additional data more difficult• Outside of normal study workflow; might be missed by site user

CONCLUSION

Rave

- **No central location exists to download files uploaded for patients**
- **New, manual processes were introduced for data coordinator**
- **Tracking amendments to case reports time consuming**
- **Only most recent file uploaded to Rave is accessible**

CONCLUSION

Mitigation

- No central location exists to download files uploaded for patients
- New, manual processes were introduced for data coordinator
- ~~Tracking amendments to case reports time consuming (Rave email triggers)~~
- Only most recent file uploaded to Rave is accessible

CONCLUSION

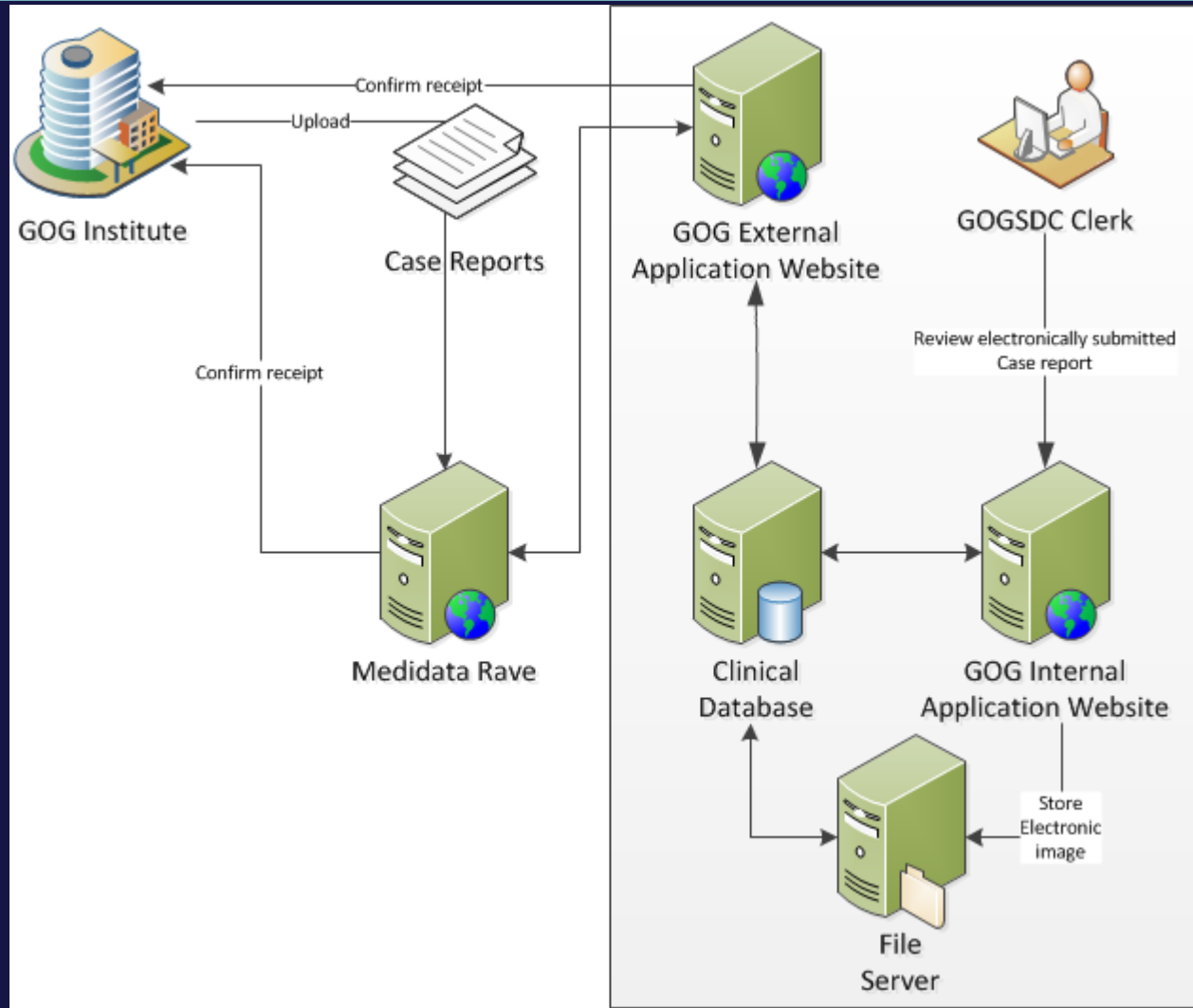
GOG

- **One study in Rave currently capturing case reports**
 - **Projected sample size of 220 patients**
 - **4 case reports per patient**
 - **Receipt of one case report roughly every two days**
- **Solutions currently in place will not scale to suit GOG needs**

LOOKING FORWARD

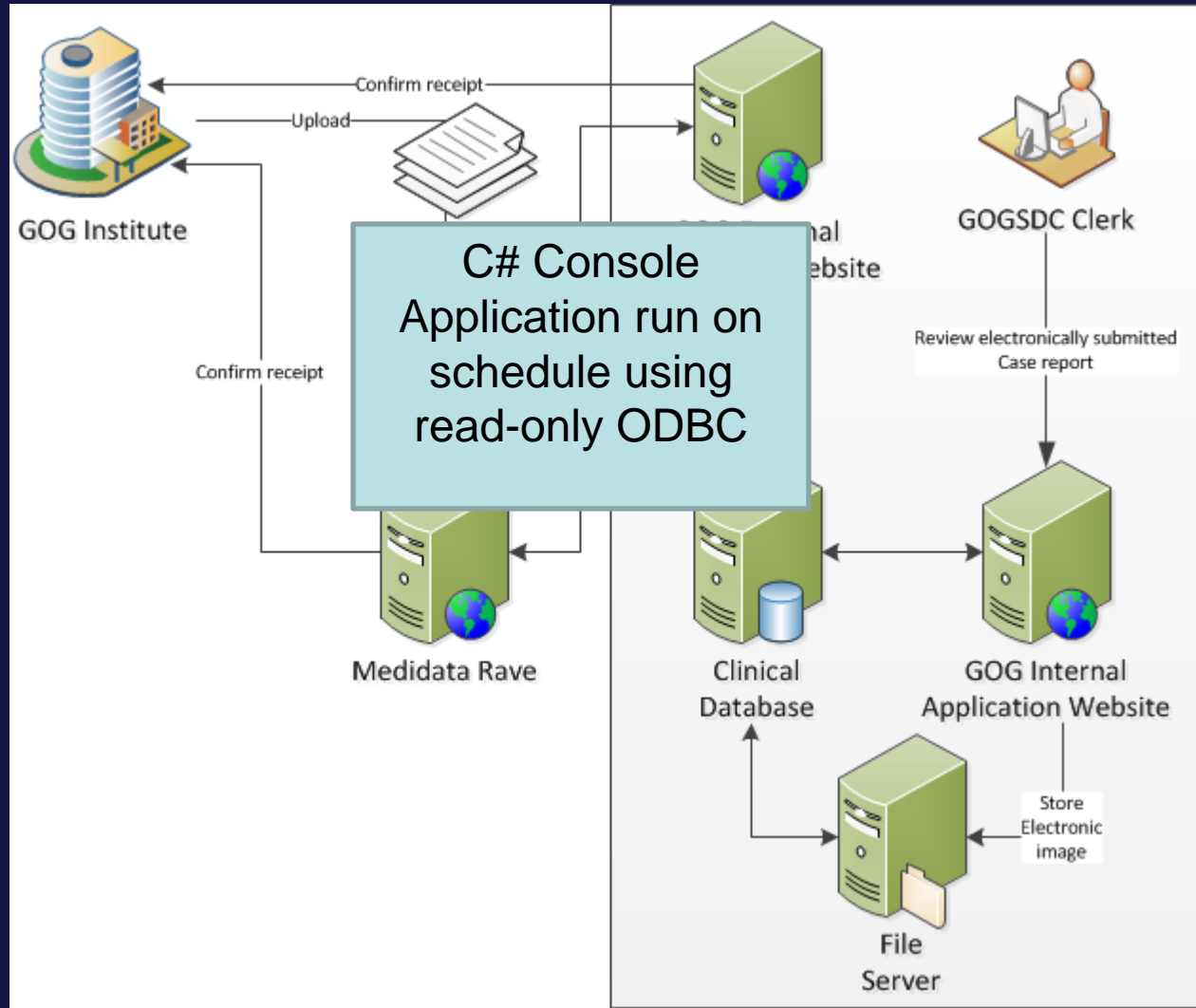
INTERIM WORKFLOW

- Uploaded files in Rave are stored in Blobs in the database
- Medidata provides a read-only ODBC for development and testing purposes



LOOKING FORWARD

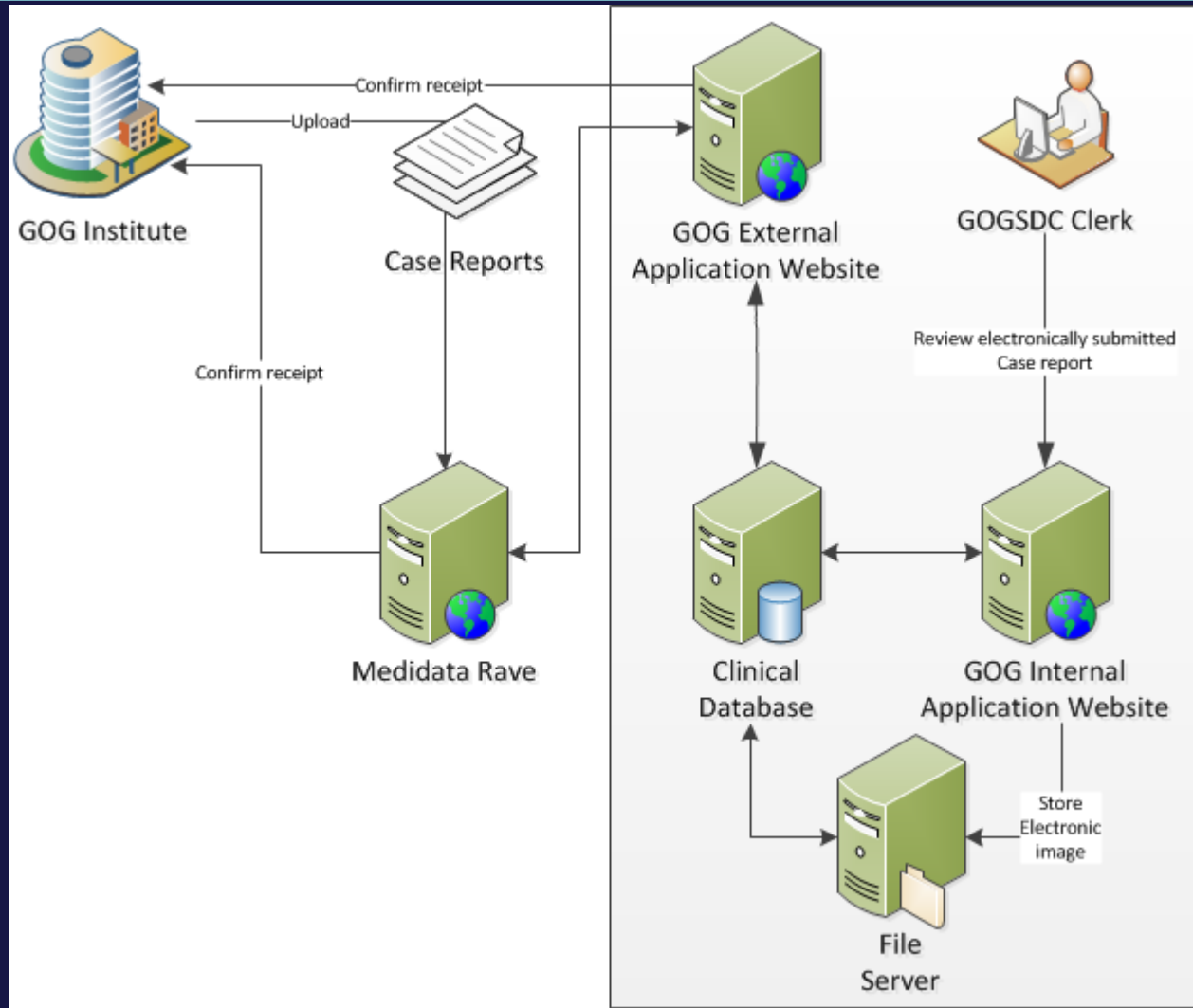
INTERIM WORKFLOW



LOOKING FORWARD

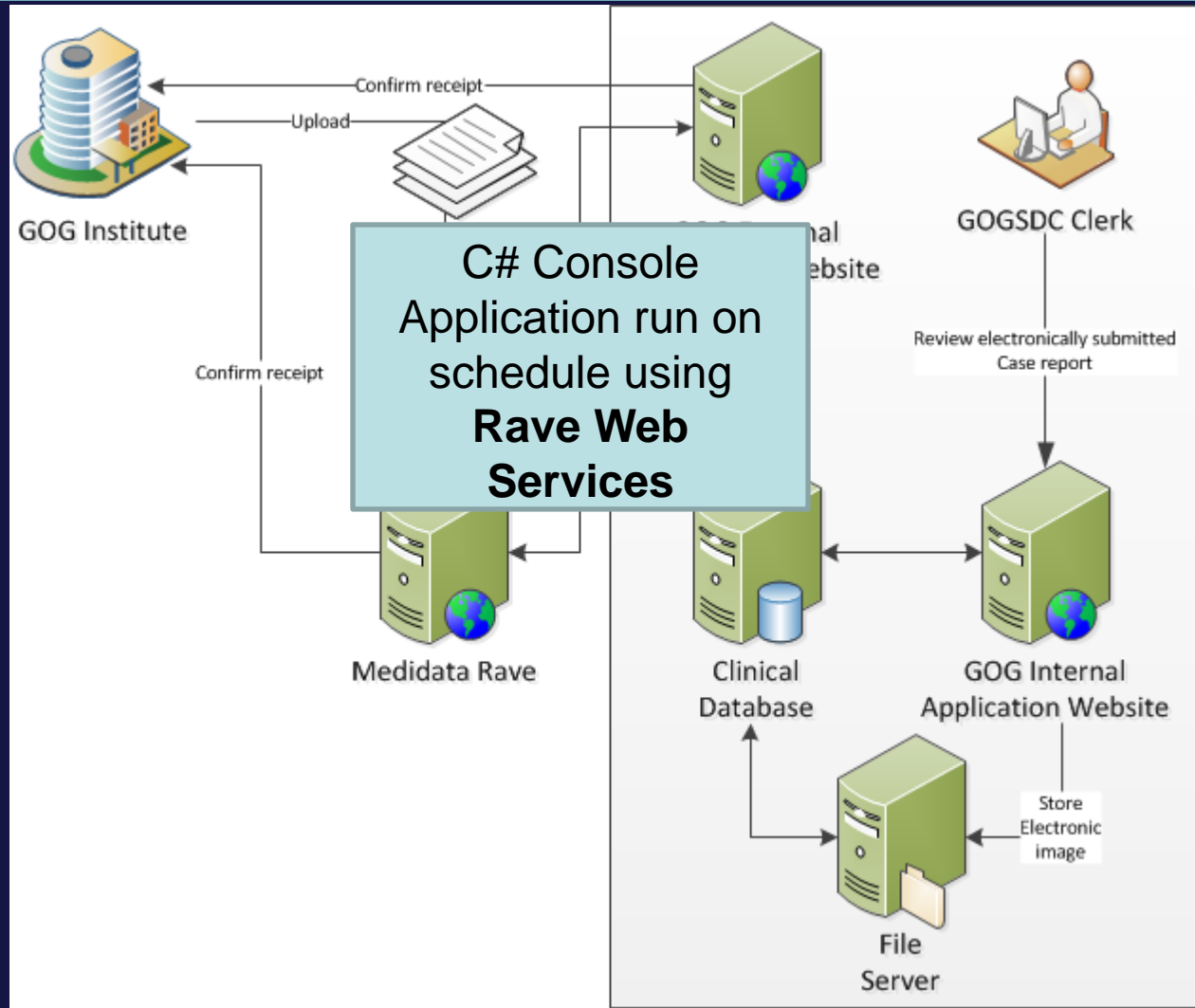
IDEAL WORKFLOW

- Medidata provides web services for interacting with both clinical and meta data
- Medidata allows clients to create custom web services to need
- GOG already leverages these services to extract necessary data from Rave



LOOKING FORWARD

IDEAL WORKFLOW



LOOKING FORWARD

- **GOG has begun to work with Medidata with the end goal of developing an extraction solution that is ideal for all involved**

QUESTIONS?

