

# HJF's Journey

LabKey

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*Advancing Military Medical Research*



# About HJF

- ✓ Private, not-for-profit organization
- ✓ Authorized by Congress in 1983
- ✓ We serve military medicine and Uniformed Services University of the Health Sciences



# Our Mission

Advancing military  
medical research



# A Brief History

In 1983, President Reagan signed congressional legislation establishing HJF

Sen. Henry M. “Scoop” Jackson championed the bill in Congress

Company renamed in his honor shortly after his death



# Where We Work

- ✓ Nearly 2,450 employees
- ✓ 100 locations worldwide
- ✓ 28 states and D.C.
- ✓ 10 foreign nations
- ✓ Nearly 90 percent work on research and clinical studies



# U.S. Military HIV Research Program

In 1985, Congress directed DoD to study HIV disease and its impact on military readiness through the **U.S. Military HIV Research Program**

Focus: Develop a globally effective HIV-1 vaccine and provide prevention, care and treatment



# HIV and the Military

An effective HIV vaccine is needed to:

- End the pandemic
- Protect deployed U.S. and allied troops
- Stabilize key partners affected by AIDS





# MHRP's Global Research Effort

Robust international  
research infrastructure and  
clinical trial capabilities

Unique combination of  
research and care in  
endemic settings

U.S. President's Emergency  
Plan for AIDS Relief (PEPFAR)





# HJF (MHRP) and LabKey Beginnings

Our journey started (a long time ago) with an article about Neutralizing Antibody (NAb) assays and LabKey

MHRP's Dr. Shelly Krebs saw that LabKey had automated analysis for others using similar NAb assays

Software like LabKey was new to MHRP researchers with “some assembly required”



Piehler et al. *BMC Immunology* 2011, 12:33  
<http://www.biomedcentral.com/1471-2172/12/33>



## SOFTWARE

## Open Access

LabKey Server NAb: A tool for analyzing, visualizing and sharing results from neutralizing antibody assays

Britt Piehler<sup>1</sup>, Elizabeth K Nelson<sup>1\*</sup>, Josh Eckels<sup>1</sup>, Sarah Ramsay<sup>2</sup>, Karl Lum<sup>1</sup>, Blake Wood<sup>2</sup>, Kelli M Greene<sup>3</sup>, Hongmei Gao<sup>3</sup>, Michael S Seaman<sup>4</sup>, David C Montefiori<sup>3</sup> and Mark Igra<sup>1</sup>

# Improved NAb Assay Tool

Shelly's team works with LabKey to demonstrate capabilities for the NAb assay using LabKey hosted environment

LabKey Services customizes the NAb assay to provide:

- 384-well plate layout
- 2 viruses per plate

## Plate Template Editor

Template Name:

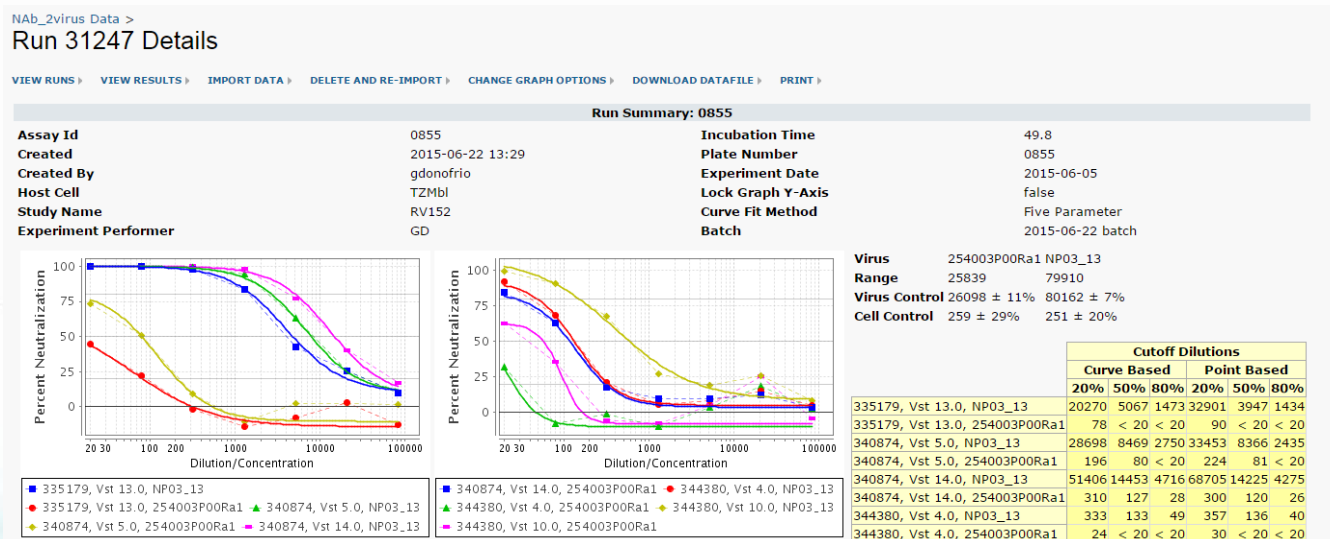
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
A																								
B																								
C																								
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G																								
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I																								
J																								
K																								
L																								
M																								
N																								
O																								
P																								

☐ Virus 1  
☐ Virus 2

New:

# Improved NAb Assay Tool – continued

- New import formats
- New export utility



Export to Excel

Name	PlateNumber	wellgroupName	StudyID	ParticipantID	SampleType	Visit	VirusName	Virus Only	Cell Only	InitialDilution	Factor	maxDilution	CurveFitMethod	curveIC20	curveIC50	curveIC80	fitError
822	822	Specimen 01:Virus 2	RV152	304728	PLEDTA	5	427299_12	35262	198	20	4	81920	Five Parameter	73.6984	21.206	-Infinity	5.2835
822	822	Specimen 01:Virus 1	RV152	304728	PLEDTA	5	816763_02	45084	225	20	4	81920	Five Parameter	214.9512	55.9652	-Infinity	11.1635
822	822	Specimen 02:Virus 2	RV152	322089	PLACD	4	427299_12	35262	198	20	4	81920	Five Parameter	100.4079	24.4345	-Infinity	12.3259
822	822	Specimen 02:Virus 1	RV152	322089	PLACD	4	816763_02	45084	225	20	4	81920	Five Parameter	70.1887	-Infinity	-Infinity	10.4624



# The (boundaries of) Automation Challenge

LabKey's modification offers huge efficiency gains for the lab's NAb assay

Almost immediately Shelly's lab looks at additional automation

Many different levels of need and opportunity exist for different laboratory groups as regards laboratory workflows



# The LabKey Word Spreads

LabKey evangelism takes hold within MHRP's labs

Other labs express both interest and doubts but agree that the product offers promise for streamlining some assays and related analyses

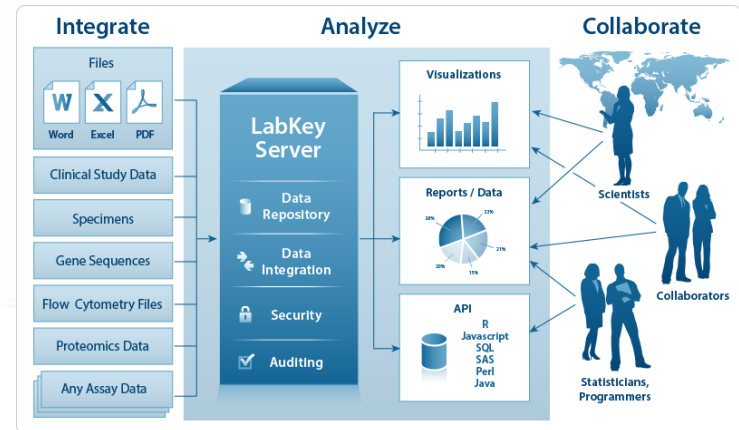
Then others within MHRP, but outside of the laboratory space take an interest...



# LabKey as an Integration Platform

The concept and value of using LabKey to provide an integrated view of Program studies takes hold

Soon we are prototyping our first MHRP protocol within LabKey as we learn the mechanics of LabKey studies...



# MHRP Studies are Primarily Overseas

Operations in multiple countries  
and often multiple locations  
within countries

Building infrastructure and  
research capacity in country is  
part of the mission

Challenges – among them are  
Information and Communications  
Technology (ICT)





# Evolution of Program Data Communications

Initially very limited

*isolated systems with periodic data transfers*

Later limited terrestrial and then satellite based

*interactive applications can suffer from reliability issues*

Now improved terrestrial but still episodic issues

*off-line computing with uplink*

Cellular technologies widespread and increased pressure for distributed operations

*mobile devices for EDC*

# MHRP (internal) LabKey Portal - WARP

Next uses within MHRP:

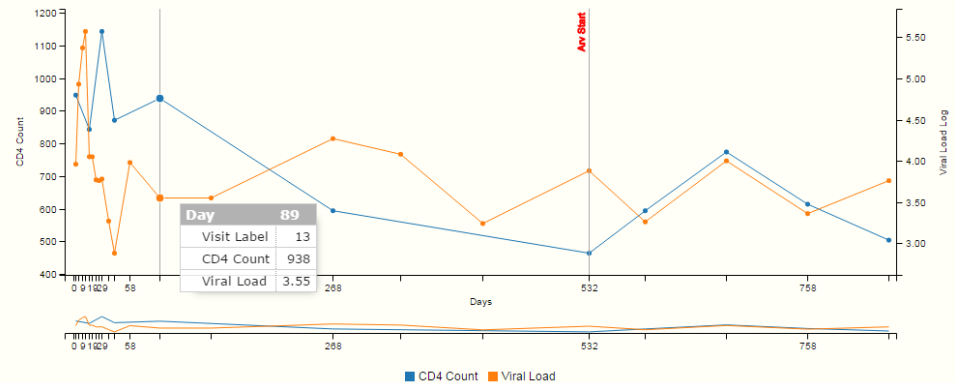
- studies
- supporting information
- site specimens
- site clinical data
- site laboratory data
- related research data
- reporting
- sharing

## WARP

WALTER REED PORTAL

CD4/Viral Load Graph

CD4 Only Viral Load Only Show Both



# LIMS Secure Web Front End

Another LabKey use within  
MHRP now in development

HIV diagnostic group running  
LabWare LIMS

LabKey Services building a  
secure web front end to  
LabWare LIMS to allow  
customers to:

- request tests
- retrieve results



# LIMS Secure Web Front End – continued

Application design emphasis  
on security and audit for  
intrinsically sensitive data

Simple UI to submit test  
requests and to provide  
specimen shipping  
information but not such a  
simple workflow

**Test Request**  
Edit existing specimens or add specimens to this test request. Click on the "ADD SPECIMEN" button to add a new specimen record. You can edit existing records by clicking directly on the row in the grid to activate the row editing tool.

Request Type:

DELETE	ADD SPECIMEN	Customer Barcode	Last Name	First Name	Date of Birth	FMP	SSN
		701235	Willis	Bruce	05/03/1962	20	111228888
		701236	Washington	Denzel	Sun Aug 04 1968		-96-7896
		701237	Stewart	Patrickgh	Tue Feb 16 2055 0...	82	111-45-6789
		701234	Willis	Hunter	Thu May 09 1996 0...	20	111-22-8888

Upload Request Details:

**Shipping Information**

Carrier:

Tracking #:



# LIMS Secure Web Front End – continued

LabKey Services designed integration to support Two-Factor Authentication (2FA)

Using Duo Security at present

Important improvement in application security, but not without its own challenges



Please complete the Two-Factor Authentication below:

A screenshot of the Duo Security login interface. At the top, there's a dark blue header with the Duo logo and a help icon. Below it, a yellow banner states "Enrollment successful! This is the Duo login prompt that you'll normally see when logging in." The main area is white and contains a "Device:" label followed by a dropdown menu showing "Android (XXX-XXX-1971)". Below this are three radio button options: "Duo Push" (which is selected and has "RECOMMENDED" in red text), "Phone call", and "Passcode". Each option has a help icon. Under the "Passcode" option, there is a text input field and a link that says "Send SMS passcodes". At the bottom right, there is a green "Log in >" button.

Enrollment successful! This is the Duo login prompt that you'll normally see when logging in.

Device: Android (XXX-XXX-1971) ▼

☒ Duo Push **RECOMMENDED** ?

☐ Phone call ?

☐ Passcode  ?  
[Send SMS passcodes](#)

Log in >

# MHRP LabKey Summary

- Laboratory workflows within the domestic lab space
- Integrated overview of disparate program data
- Uses in overseas sites, communications permitting
- Learning and adoption curves, standardization, coordination and staffing
- External collaborators



# ACESO

(Austere environments Consortium for Enhanced Sepsis Outcomes)





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(Austere environments Consortium for Enhanced Sepsis Outcomes)



**Aceso (Ἀκεσώ)**  
Greek goddess of  
healing wounds and  
curing illness

# Severe Sepsis

Bloodstream infection by any pathogen  
(bacterial, viral, fungal, parasitic, etc.) leading to:

- an overwhelming inflammatory response
- septic shock with damage to vital organs

A leading cause of mortality in both developed  
and developing countries

Supportive care, ICUs in developed countries

Involved in >10% military multi-trauma patients



# Aims of ACESO

Improve adult patient survival in austere settings through:

- early recognition of disease
- identifying useful biomarker panels
- evidence-based clinical management



# The ACESO Network

The collaborative research effort includes the NMRC, LLNL, American and Ugandan universities, and U.S. Navy medical laboratories in Egypt, Cambodia, and West Africa.



# ACESO and LabKey

Initial phase:

- aggregate clinical and laboratory data from Program sites

Follow on:

- automate lab workflows
- automate QC processes
- reporting



**Duke**Medicine

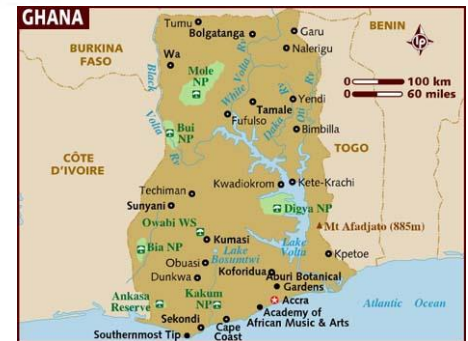
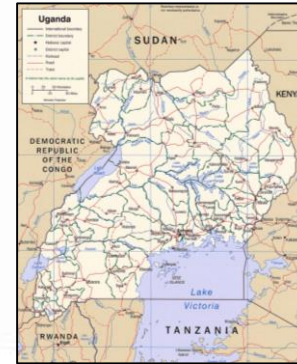




# ACESO Futures – More than Sepsis

Future challenges:

- more remote locations
- more austere conditions
- disconnected data collection
- mobile medical teams



# Research Data Trends

## clinical data

paper CRFs

electronic CRFs

mobile electronic CRFs

raw data

wearables



## laboratory data

volume

complexity

analytics

collaboration

Items	Abbreviation	Units
White blood cell	WBC	10 <sup>9</sup> /uL
Lymphocyte	LYM#	10 <sup>9</sup> /uL
Mid-Cell	MID#	10 <sup>9</sup> /uL
Granulocyte Percent	GRAN%	10 <sup>9</sup> /uL
Lymphocyte Percent	LYM%	%
Mid-Cell Percent	MID%	%
Granulocyte percent	GRAN%	%
Red blood	RBC	10 <sup>12</sup> /uL
Hemoglobin concentration	HGB	g/dL
Hematocrit	HCT	%
Mean cell volume	MCV	fL





# HJF and LabKey Summary

flexible standard framework  
open source model and technologies  
community and professional services  
complements existing applications  
collaboration/communication  
“line-of-business” for research labs



# Acknowledgments

## LabKey Software

Josh Eckels, Britt Piehler, Karl Lum, others

## MHRP

Dr. Shelly Krebs, Dr. Leigh Anne Eller and many others

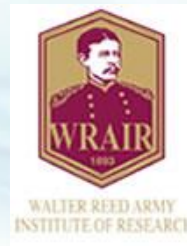
## ACESO

Janice Hepburn, others

## HJF IT Services

Chris Schoening, Nickhat Zafar, IT Operations team

## US Government Sponsors and Collaborators



# Questions & Discussion

