ALLIANCE FOUNDATION TRIALS, LLC

Site Study Start-Up Requirements for AFT Studies

Alicia Quirke, Site Manager

Agenda

- Pre-Study
- Site Selection
- Site Start-up
  - Documents
  - Training
- Activation

Pre-Study

- Prelim Site list created based on previous study accrual with AFT and Alliance studies, Alliance membership in good standing, etc.
  - Sites are sent out an email to inquire about potential interest in participation
- Invitation includes:
  - Brief protocol title and description
  - CDA template
- Sites will have to complete and send back the CDA within 5-10 business days in order to obtain full protocol and feasibility for review/completion

Pre-Study - Feasibility

- AFT has recently submitted a general feasibility via survey monkey link
- The purpose of this general feasibility is to keep on record standard site information that would mostly be consistent throughout multiple studies
- Once general feasibility is collected, only a study specific feasibility will be issued to sites for potential participation
- Feasibility is to be sent back within 5-10 business days

Pre-Study – Feasibility

- AFT studies are open to Alliance Members only
- Alliance site membership must be in **good standing**
- Alliance sites must be meeting accrual targets
  - AFT accruals can count towards Alliance accrual credits
- Drug can only be shipped to one central location per site
- If multiple site locations are listed on a feasibility questionnaire, site/drug management plans are to be submitted to the AFT Site Manager for review/ approval to ensure proper drug management and document practices
- There must be one 1572 (with satellite sites listed) with one location listed for drug shipments
- Site should be able to accommodate central monitoring (similar to Alliance audit practices)
- An Investigator can be a PI for multiple sites within a network, if necessary

Site Selection

- If feasibility answers and site dynamics are sufficient, a formal selection email will be sent to the site for participation into the study
- Included in the initial selection email will be a Site Information Sheet (template) that will require site and contact information and also outline system access

Site Information Sheet (SIS)

- Required to be able to enter site, contact and system access into our electronic systems
- Required to be completed and submitted first before study templates are sent out
- Site information sheets won't always be required for full completion
  - We are currently building up our Clinical Trial Management System (CTMS) with AFT site/personnel information and will be able to review for site participation

CTMS Site Information Sheet

Protocol Number:

PI Last Name:

Contact completing form: (Name and Email)

* = required field

	Location Type*	Name of Institution as would appear on the 1572*	Address Line 1*	City*	State*	Country*	Postal Code*	Main Phone #*	Main Fax #	IRB	Comments
Main Site Information	Select a Location Type from the drop-down list									Select IRB Type	
Name of Main Alliance Member *(if applicable)*	Select a Location Type from the drop-down list									Select IRB Type	
Drug Shipment *(if different than Main site)*	Select a Location Type from the drop-down list									Select IRB Type	
Additional Locations	Select a Location Type from the drop-down list									Select IRB Type	
Additional Locations	Select a Location Type from the drop-down list									Select IRB Type	

CTMS Site Information Sheet

Protocol Number:

PI Last Name:

Contact completing form: (Name and Email)

	Contact Type	Last Name	First Name	Prefix	Address Line 1	City	State/Province	Postal Code	Country	Phone #	email (required)
Principal Investigator	Select a Contact Type from the drop-down list			Select a prefix from the drop-down list							
Sub-Investigator	Select a Contact Type from the drop-down list			Select a prefix from the drop-down list							
Sub-Investigator	Select a Contact Type from the drop-down list			Select a prefix from the drop-down list							
Lead Site Coordinator	Select a Contact Type from the drop-down list			Select a prefix from the drop-down list							
Site Coordinator	Select a Contact Type from the drop-down list			Select a prefix from the drop-down list							
Other	Select a Contact Type from the drop-down list			Select a prefix from the drop-down list							
Pharmacist	Select a Contact Type from the drop-down list			Select a prefix from the drop-down list							

Systems Access and Training (Refer to Systems Access Tab below for

Protocol	GCP	eTMF	BioMS	Argus	IRT	EDC
X	X	X	X	X	X	X

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Start-up

- When SIS is received and confirmed complete, a welcome email will be sent by AFT Site Management that includes the following:
  - Outline of study requirements for activation
    - Documents
    - Training
  - Study templates
  - Applicable study manuals
  - AFT CRA contact

Clinical Study Agreement (CSA)

- A separate email with the CSA template will be sent under the cover of contracts@alliancefoundationtrials.org

- All budget and contract questions should go to the contracts group at AFT

Essential Documents for IP Release

- Form 1572
  - Signed by PI
  - Two available templates
- Protocol / Protocol Amendment Signature Page(s)
- IB Acknowledgement Page
- Signed Clinical Study Agreement (CSA)
- PI CV (signed within 3yrs) / Medical License
- PI signed Financial Disclosure Form (FDF)
- CV (signed within 3yrs) / Medical License
  - Required for all individuals listed on the 1572
- Signed FDF for all individuals listed on the 1572
- Laboratory Certification(s) / Laboratory Reference Ranges
  - For all Local Labs listed
  - Can submit CLIA and/or CAP
- Laboratory Director CV(s)/ Medical Licenses(s)

IRB Documents Required for IP Release

- IRB approval letter of Protocol, PI and Informed Consent Form (ICF)
- IRB approved Site ICF
  - AFT MUST review the site ICF template BEFORE submission to the IRB
- IRB Roster
- Documentation of Non-Voting Status, if applicable
- Study Related documents (patient facing), if applicable
- AFT utilizes Quorum as the Central IRB

Quorum

Additional Essential Docs for Activation

- Delegation of Authority Log
- GCP training (completed within 3yrs) for all relevant study staff
  - Acceptable certificates can be found:
    - http://www.transceleratebiopharmainc.com/gcp-training-attestation/
  - Also accept NIH training (free)
    - https://gcp.nihtraining.com/
  - Other certificates should be submitted to the Site Manager for pre-approval
  - GCP training will be monitored for expiration and new certificates will be required every 3yrs (or per site policy)

Submission of Essential Documents

- All essential documents will be uploaded by the site into the site facing eTMF

siteZONE

Welcome, Lisha Quirke Sign Out

Randomized Phase II Trial Evaluating the Optimal Sequencing of PD-1 Inhibition with Pembrolizumab (MK-3475) and Standard Platinum-based Chemotherapy in Patients with Chemotherapy naive stage IV Non-small Cell Lung Cancer	Study	Site ID	Site Name	Sponsor	CRO
	AFT-09	US-101001-Bryan Pouliot	[redacted]	UAT Sponsor	UAT Partner

Study Information | Document Library | Tasks | Acknowledgements

Search Documents

Filter Documents by...

Task Owners

- Group Tasks (11)

Task Type

- Upload (11)

Due Date

- Next 30 Days (11)

11 items found

Add A Document

Upload - IP Shipment Documentation (Site Level)

Upload Document

Due Date:	14-May-2016
Task Creation Date:	27-Apr-2016
Sent To:	All Users

Due in 16 days

Upload - Acceptance of Investigator Brochure - Bryan Pouliot

Download Template Upload Document

Due Date:	14-May-2016
Task Creation Date:	27-Apr-2016
Sent To:	All Users

Due in 16 days

Upload - Delegation of Authority Log

Upload Document

Due Date:	14-May-2016
Task Creation Date:	27-Apr-2016
Sent To:	All Users

Due in 16 days

Site Training Requirements

- Protocol Training (required for all)
- Medidata RAVE (EDC) ~1-1.5hrs
  - PI required
  - Data entry person required
  - back-up for each
- Argus (Safety Database) ~35min
  - PI required
  - Data entry person required
  - back-up for each

Site Training Requirements

- Wingspan SiteZone (eTMF/ISF) ~5-6 min
  - At least one site staff member required to train for site activation (suggest back-up)
  - PI required
- Oracle IRT ~2hrs
  - At least one site staff member required to train for site activation (suggest back-up)
  - PI required (but not for site activation)
- BioMS (Biospeciman tracking) ~10min
  - At least one site staff member required to train for site activation (suggest back-up)
  - PI required (but not for site activation)

SiteZone ®

- Study invitation will be sent via email to applicable staff outlined in the SIS
- Staff will click on the “accept invitation link” and be brought to an internet page to select one of the following:
  - I am already a SiteZone user
  - I am using SiteZone for the first time
- Using your email as the user name, create a password that contains at least 8 characters with at least one upper case and one #
- Once user name and password are accepted – you can navigate to https://sitezone.mywingspan.com to log into the system
- SiteZone training consists of a 5-6 minute video and will play upon first log-in to the system

From: Wingspan TMF Testing [noreply3@mywingspan.com]
To: Quirke, Alicia Marie
Cc:
Subject: You have been invited to SiteZone!
Sent: Tue 05-Apr-16 11:10

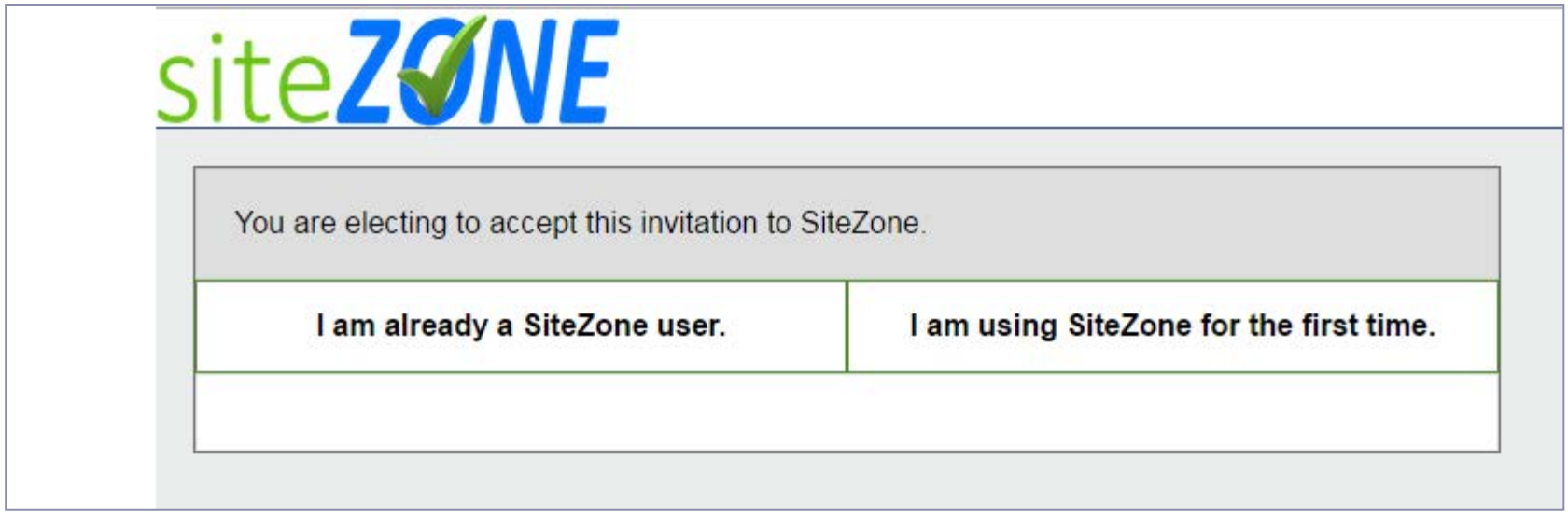
Dear aquirke@partners.org,

Welcome, you have been invited to SiteZone for study: NCT01420666, site: 2587

To accept the invitation, click the following url:
https://sitezone23.testing.mywingspan.com/sitezone/invitation.html#/accept/aft/1022AF760000000000008C21/eyJhbGciOiJIUzUxMiJ9.eyJzdWIiOiJ1aWQ9c3o6MWNkZjQwZmQtZjYwMS00ZmYwLTk5OGItMWM1
MTAwNSwiaWF0IjoxNDU5ODY5MDA1fQ.VVX8KhPFnFghRhleTAAjbaCKa4zw3GFYnmehIXWOBEg0ijU12ppxn_3wNoxidjatJBda2ZZzu59buwri9rjHGw

To reject the invitation, click the following url:
https://sitezone23.testing.mywingspan.com/sitezone/invitation.html#/reject/aft/1022AF760000000000008C21/eyJhbGciOiJIUzUxMiJ9.eyJzdWIiOiJ1aWQ9c3o6MWNkZjQwZmQtZjYwMS00ZmYwLTk5OGItMWM1N
MTAwNSwiaWF0IjoxNDU5ODY5MDA1fQ.VVX8KhPFnFghRhleTAAjbaCKa4zw3GFYnmehIXWOBEg0ijU12ppxn_3wNoxidjatJBda2ZZzu59buwri9rjHGw

Confidentiality Notice: This email and its attachments or references may contain privileged and confidential information and/or protected health information (PHI), and is for the sole use of the intended recipient(s). If you are not the intended recipient, please contact the sender by reply email and destroy all copies of the original message.



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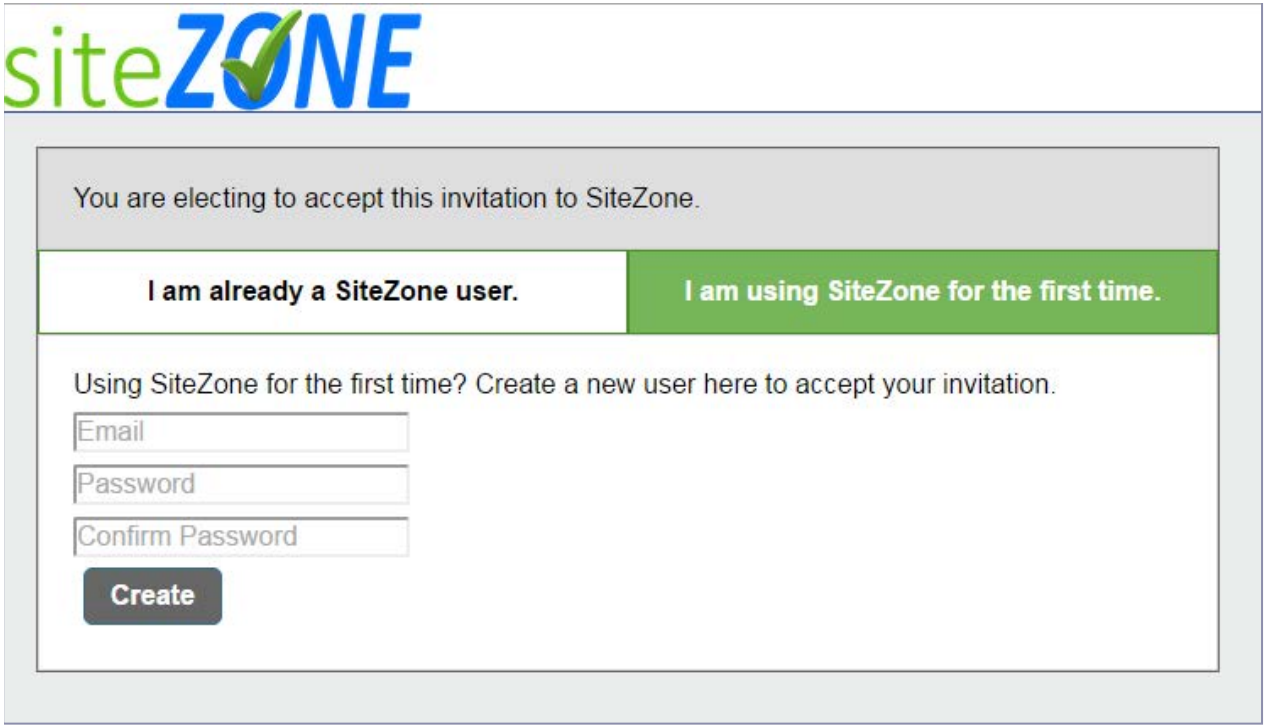

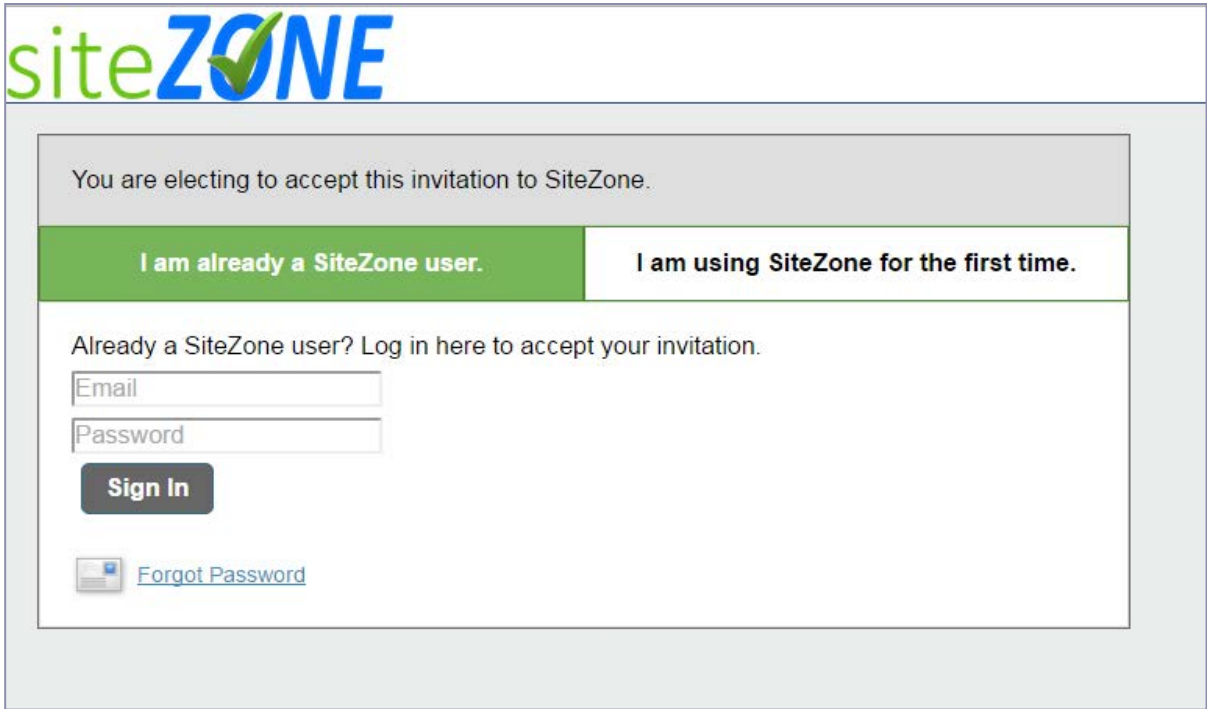

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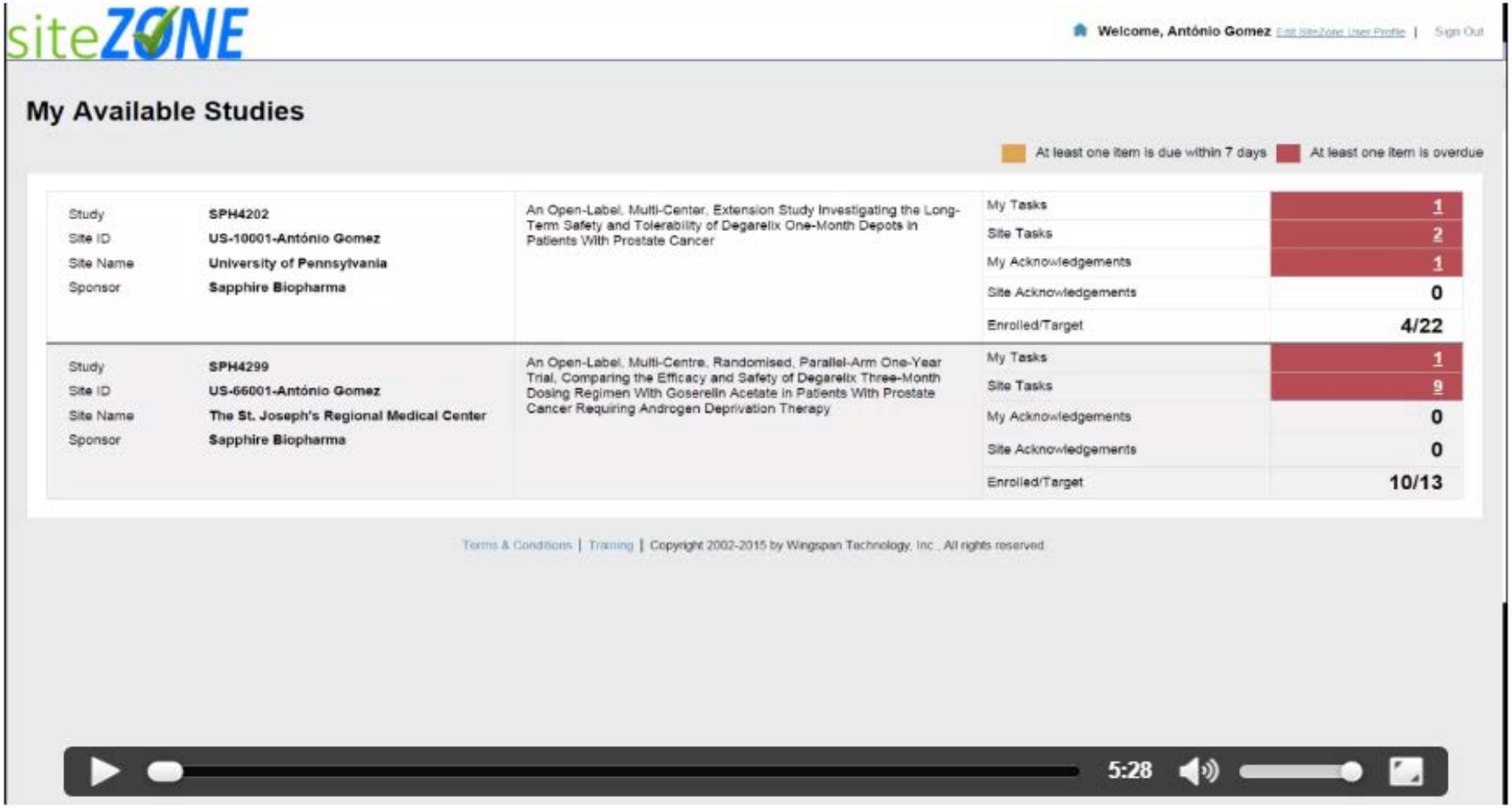
siteZONE

SiteZone User Training

Please press the Play button to watch the following short video to familiarize yourself with SiteZone. You will not be able to proceed to the SiteZone Home Page until you have completed the entire video.

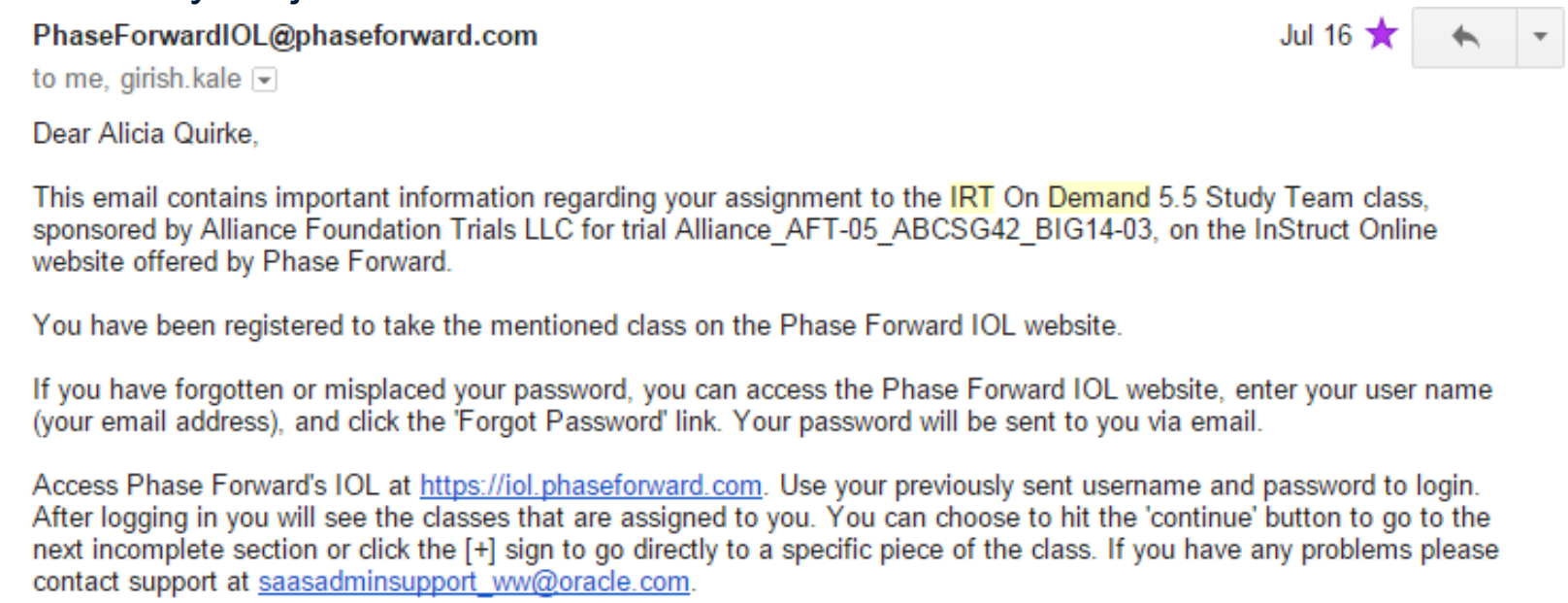


Medidata Rave® EDC Training
Training for Sites

- Medidata Rave® training (i.e. eLearning)
  - Study invitation will be sent via email to applicable staff outlined in the SIS
  - Study personnel access to Rave is maintained by the AFT CTMS system
  - All staff entering data in Rave must complete required eLearning courses prior to study access
  - eLearning can be completed and tracked across URLs so required modules only need to be completed once per role
    - If the required iMeditada training has been completed for a previous study (AFT or Alliance)
  - All eLearning courses are available for review any time

Oracle IRT –Training

- Email will be sent with user name and temporary password and then a link to training website where assigned modules will need to be completed before access is granted.
- Check your junk mail!!!!



PhaseForwardIOL@phaseforward.com Jul 16

to me, girish.kale

Dear Alicia Quirke,

This email contains important information regarding your assignment to the IRT On Demand 5.5 Study Team class, sponsored by Alliance Foundation Trials LLC for trial Alliance_AFT-05_ABCSG42_BIG14-03, on the InStruct Online website offered by Phase Forward.

You have been registered to take the mentioned class on the Phase Forward IOL website.

If you have forgotten or misplaced your password, you can access the Phase Forward IOL website, enter your user name (your email address), and click the 'Forgot Password' link. Your password will be sent to you via email.

Access Phase Forward's IOL at https://iol.phaseforward.com. Use your previously sent username and password to login. After logging in you will see the classes that are assigned to you. You can choose to hit the 'continue' button to go to the next incomplete section or click the [+] sign to go directly to a specific piece of the class. If you have any problems please contact support at saasadminsupport_ww@oracle.com.

Training cont.

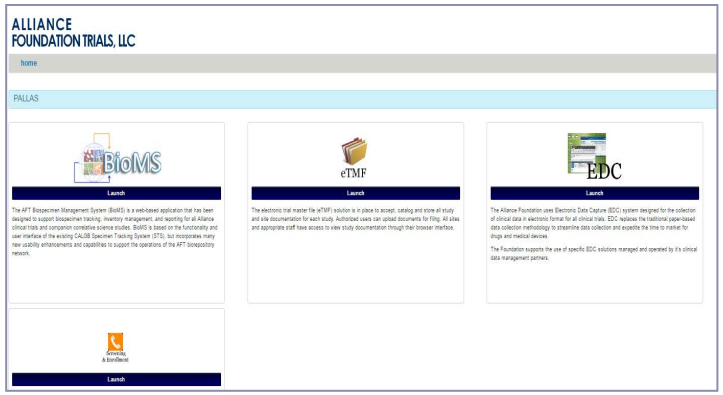
- Sites will be granted access to AFTs Learning Management System (LMS) where videos will be required to review for the following systems:
  - Argus (Safety)
  - BioMS (Biospeciman tracking)
  - Veeva (eTMF) – PALLAS only
- Once complete, AFT will provide Vendors site information for account requests.
- Site Staff will receive individual accounts and instructions on how to log-in and change passwords, etc.

Portal vs LMS

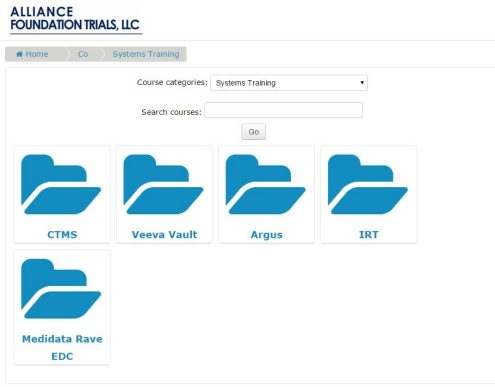
- LMS (Learning Management System) is a website that houses training videos and protocol reviews
- The AFT portal is a website where the LIVE links are found to gain access to AFT systems
- The systems are accessed at two different web addresses
  - The **portal** is accessed at https://alliancefoundationtrials.org/
  - **LMS** is accessed at https://**lms**.alliancefoundationtrials.org/

What am I trying to do?	Which website should I access?	
	LMS	AFT Portal
I'm trying to complete my protocol **training**…	✓	
I am trying to **access** an AFT **system**, such as the eTMF…		✓
I'm trying to complete my Argus, BioMS, and/or eTMF **training**…	✓	

The AFT Portal
https://alliancefoundationtrials.org/



Learning Management System (LMS)
https://lms.alliancefoundationtrials.org/



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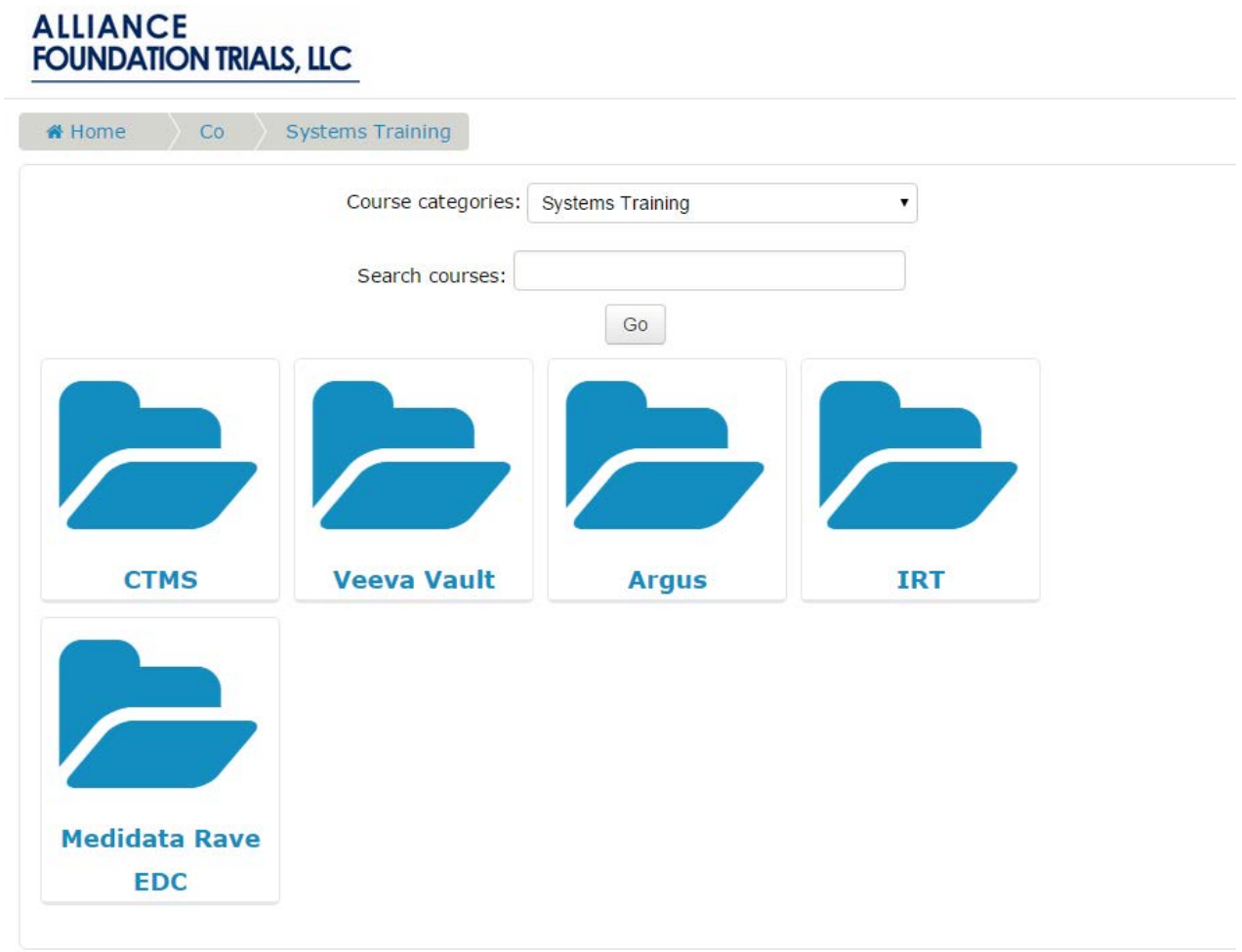
AFT Learning Management System (LMS)



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Site Training Certificates

- If a site personnel has completed training on the system(s) for a previous AFT trial and are active in the system, that training will carry over to other AFT trials and will not have to be repeated.
- Certificates of training completion will be filed in the eTMF/ISF for all studies.
- All training must be completed within 30 days of site activation

FOR ISSUES RELATED TO THE SYSTEMS PLEASE CONTACT

techsupport@alliancefoundationtrials.org

Site Supplies

- Biorepository Lab Kits
  - Please order 3 screening and Day 1 Cycle 1 (D1C1) kits **ASAP** as it can take up to 5-10 business days for delivery
  - Email afbhelp@bmi.wustl.edu and provide recipient name, shipping address, protocol number and type of kit (screening, C1D1)
  - Supplies MUST be on-site before site activation/screening can occur
- Investigational Product
  - Shipped to site's central pharmacy once all essential documents have been collected, reviewed and signed off

Site Initiation Visit (SIV)

- The SIV will be conducted prior to patient enrollment and after the site receives IRB approval, has a fully executed Clinical Study Agreement (CSA) and regulatory documentation is (almost) complete.
  - Every effort will be made to conduct SIVs when IP is on site
- SIVs can be conducted in two ways:
  - On-site visit
  - Webinar/Recording

Site Activation

- A site can begin to enroll patients into the AFT study when the following have occurred and the site receives a **Site Activation Notification.**
  - Essential Documents approved for IP release and IP received at site (includes IRB approvals and CSA)
  - Protocol, GCP and system trainings have been confirmed as complete for all applicable site personnel and log-ins issued
  - Lab kits on site
  - SIV conducted and documented
- Sites can NOT consent/screen patients until the notification has been received.

SITE ACTIVATION NOTIFICATION TEMPLATE

TO: <Site Principal Investigator>

FROM: <CRA>

SUBJECT: Site Activation: <Site Name/Number>

PROTOCOL: <insert>

DATE: <Date>

Dear Dr. <Site Principal Investigator>,

Your site, <Name>, has completed all the below study requirements for site activation. This notice serves that you are authorized to begin enrolling patients into the XXX Study.

- ✓ IP Release and receipt at Site,
- ✓ Lab Kits on site,
- ✓ Protocol training by PI and all staff listed on DOA,
- ✓ Argus Safety Database training by PI and at least one other,
- ✓ Interactive Response Technology (IRT) by at least one study staff,
- ✓ eTMF by at least one study staff,
- ✓ BioMS (Biospecimen Repository) by at least on study staff,
- ✓ Medidata RAVE EDC training by PI and at least one other,
- ✓ GCP training for PI and all staff listed on DOA,
- ✓ SIV Complete with no major findings.

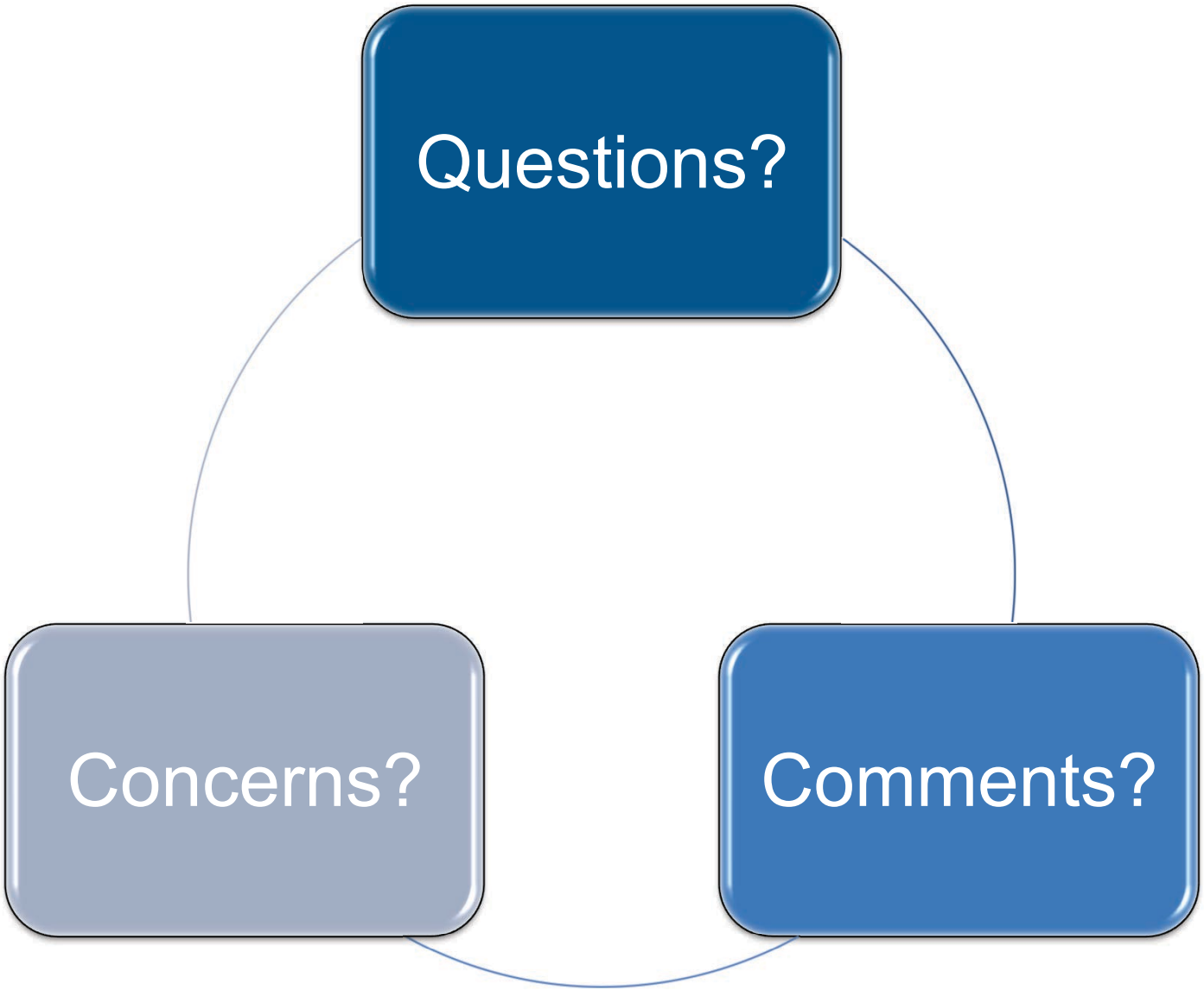
I will be your point person for any questions you may have during the course of the study and you can reach me at <insert contact information>. We look forward to working with you!

Sincerely,

<CRA, phone number, email address>

AFT Site Management Team

- Alicia Quirke, Site Manager
  - 617-525-7130
  - aquirke@alliancefoundationtrials.org
- Hillary Wilson, CRA, Site Management
  - 617-525-7137
  - hwilson@alliancefoundationtrials.org
- Naomi Toavs, CRA
  - 617-732-8016
  - ntoavs@alliancefoundationtrials.org


Questions?
Concerns?
Comments?