ALMAC

IXRS®
Interactive Voice and Web Response System

MTN Annual Meeting – ASPIRE Trial

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Materials Planning and Supply Chain Lead

MTN Regional Meeting:
3-October-2012

Overview

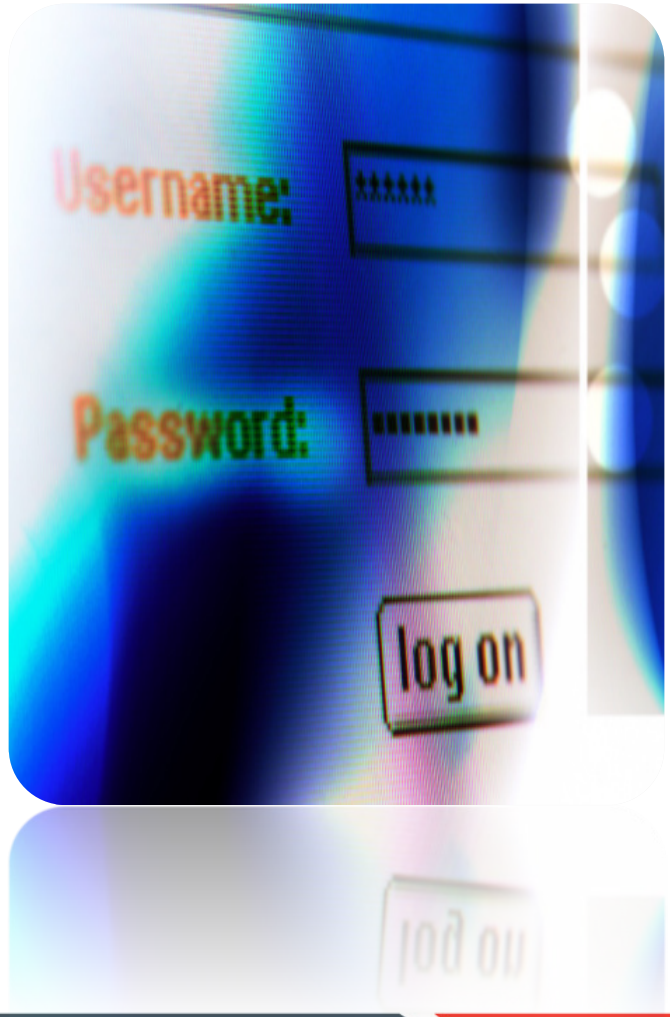
- Introduction to Almac Services for IPM027
- IXRS® User Roles and Responsibilities-Access
- Guide to Using the System
- Technical Support Available

IPM027-Modules Used

- Participant Drug Management
- Participant Screening
- Participant Randomization
- Participant Scheduled Resupplies
- Participant Unscheduled Resupply
- Medication Replacement
- Participant End of Product and End of Study
- IXRS® Training
  - Once system is live Almac can offer CRA training on the demonstration system
- 24 Hour Technical Support

Accessing the IXRS®

- Each user will have a unique numeric User ID and Password
- A Quick Reference Document (QRD) provided to each user lists the secured web address and toll-free telephone numbers
- Upon first login, user is prompted to change 7-digit password
- Same User ID and password to access both phone and web system
- The menu options available to each user is based on their study role



IXRS® User Roles Available

- **Blinded Sponsor / Admin**
  - Study Site Management
- **Research Centre Personnel**
  - All Participant-related IXRS® modules
    - Note Participant Un-blinding is only applicable for Investigator
- **Product Manager** – Un-blinded Supply Chain Manager
  - Carton Release (from Temp Excursion or Damaging) and drug-related options in Study Site Management
- **Investigator**
  - All IXRS® modules including Participant Un-blinding (ex. Primary Investigator)
- **Medical Safety Un-blinding (Global Un-blinding)**
  - Participant Un-blinding for participant randomized treatment

Centre Activation & Initial Shipment

Upon IXRS® Centre Activation:

- Each Centre User will receive their access letters via email or courier **upon confirmation from IPM Project Manager**.
- Access letters will contain:
  - User ID
  - Details on how to obtain password
  - Details on how to download the Quick Reference Document (User Manual)
  - How to contact technical support
- Activation of centre by Client within the IXRS® will trigger the initial drug shipment of study medication

Quick Reference Document-Cheat Sheet

Refer to the Quick Reference Document for...

- IXRS® Web Address and/or Toll Free Telephone Number
- IXRS® Menu Options (based on User Role)
- Study code required for logging in the IXRS® and contacting Technical Support
- Instructions for accessing IXRS® Technical Support
- Practice IXRS® instructions:
  - *A practice environment is available for users to become familiar with the phone and web system prior to performing in the study live environment.*

Centre Menu Options in the IXRS®

Register a new Participant

Activities related to existing Participants

- Register this participant as screen failure
- Randomize this participant into the study
- Register scheduled resupply visit for this participant
- Register unscheduled resupply visit for this participant
- Replace lost or damaged product for this participant
- Register the end of investigational product for this participant
- Register the end of study for this participant

Confirm Receipt of Product

Emergency Un-blinding Information

Only Accessible by Investigator Or Global Un-blind (Medical Safety)

Confirming Receipt of Product

- Select ‘Receipt of Product’ Menu Option
- Enter the shipment number
- Confirm amount of cartons contained within the shipment is correct
- Enter the date the shipment was received
- Confirm if shipment was received intact and undamaged

Option 1) If specific carton number was damaged as a result of being out of temperature range

Option 2) If the entire shipment is physically damaged

Option 3) If specific carton number is physically damaged

Option 4) If specific medication numbers were damaged

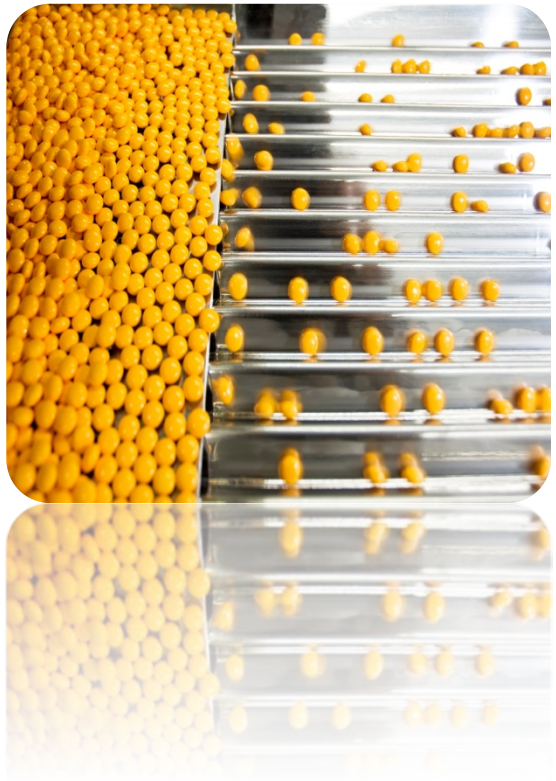
Note: medication numbers refer to the specific ring numbers contained in a carton

Important Reasons to confirm shipments in the IXRS® …

- It provides supplies traceability
- Registers medication as having arrived at site or depot
- Reports shipment condition
- Enables IXRS® to dispense medication to participants at centre
- Without Shipment Acknowledgement
  - Medication will not be Available at Centre
  - IXRS® will not have an accurate inventory count
  - It may jeopardize participation medication assignments such as randomization or scheduled resupply

Managing the Drug Supply

- Trigger and resupply levels are determined during study start-up.
- With IPM approval, trigger and resupply levels can be adjusted to suit the centre's recruitment level.
- When triggers are met, IXRS® will initiate a drug order to established centre resupply levels.
- In addition, the system will be using participant drug use projections. Baseline for projections is participant randomization date.



IXRS® Participant Transactions

- **All transactions will produce a confirmation sent to the users fax or email.**

	INPUTS	OUTPUTS
Initial Participant Entry/ Screening	Screening Date Participant date of birth *Note: For unknown DOB's, user will enter DOB in DD-MM-YYYY where 01 is for the day, 01 is for the month and the year (YYYY) will be kept within protocol age range under discretion of users.* Participant Initials	***Participant ID*** ***Confirmation***
Participant Screen Failure	Participant ID Failure Date	•**Confirmation**
Participant Randomization	Participant ID Confirm to randomize participant	•**Medication (Ring) Number** •**Confirmation**

IXRS® Participant Transactions

	INPUTS	OUTPUTS
Scheduled Resupply	•Participant ID •Confirm visit week number and visit date *Note: system determines the next expected visit and visit date for participant based on transaction date and randomization date*	•New Medication (Ring) Number •Confirmation
Replace Medication	•Participant ID •Lost/Damaged Medication (Ring) Number	•New Medication Number (Ring) •Confirmation
Unscheduled Resupply	•Patient ID •Confirm user wishes to proceed with transaction	Confirmation

IXRS® Participant Transactions

	INPUTS	OUTPUTS
End of Investigational Product	•Participant ID •Enter the date the participant ended the investigational product •*Note: Users will access this module to acknowledge that the medication number dispensed at last visit directly prior to completion (Week 100) or discontinuation is returned back at the center*	•Confirmation
End of Study	•Participant ID •Enter the end of study date for which participant completed the study or was discontinued from the study •*Note: the End of Product Module must be utilized.*	•Confirmation

IXRS® Participant Transactions

Investigator Confirmation will not display treatment.

Medical Safety Un-blinding Confirmation will display treatment.

Participant Un-blinding

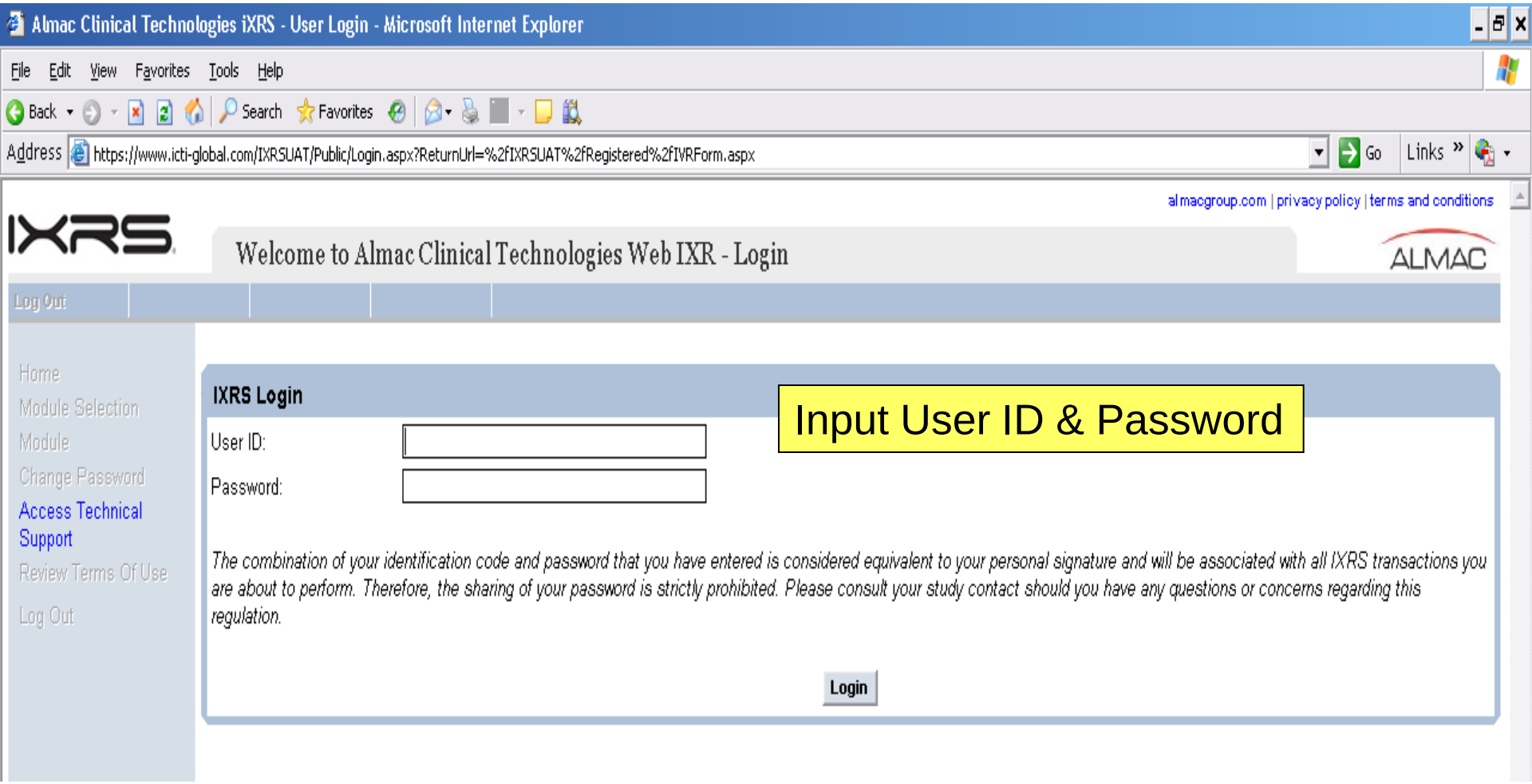
INPUTS	OUTPUTS
Participant ID, DOB	**Announcement of Participant's Randomized Treatment Arm / Confirmation (fax/email)**

Emergency Un-blinding

- Only the Principal Investigator at each centre will receive access for Emergency Un-blinding
- Once a participant is un-blinded by Investigator they **will no longer** be eligible for drug assignments
- If the Principal Investigator is unavailable in an emergency, the Medical Safety should be contacted.
  - The Medical Safety also has access to carry out Emergency Un-blinding (Global Un-blind Access)
  - Once a participant is un-blinded they **will NOT be** eligible for drug assignments

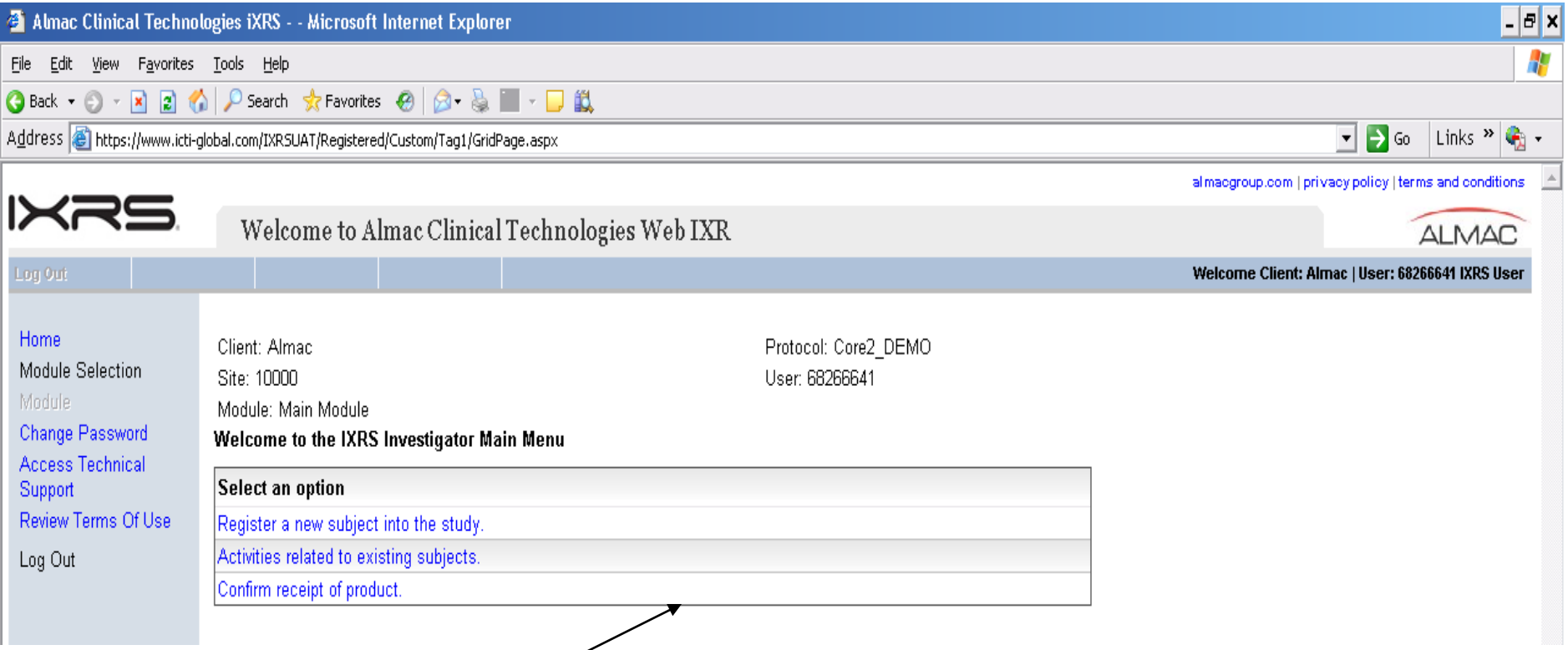
Using The Web

Log-on


Almac Clinical Technologies iXRS - User Login - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.icti-global.com/IXRSUAT/Public/Login.aspx?ReturnUrl=%2fIXRSUAT%2fRegistered%2fIVRForm.aspx
Go Links
almacgroup.com | privacy policy | terms and conditions
IXRS
Welcome to Almac Clinical Technologies Web IXR - Login
ALMAC
Log Out
Home
Module Selection
Module
Change Password
Access Technical Support
Review Terms Of Use
Log Out
IXRS Login
User ID:
Password:
Input User ID & Password
The combination of your identification code and password that you have entered is considered equivalent to your personal signature and will be associated with all IXRS transactions you are about to perform. Therefore, the sharing of your password is strictly prohibited. Please consult your study contact should you have any questions or concerns regarding this regulation.
Login

Centre User Main Menu

Note: this is just a sample, not study specific

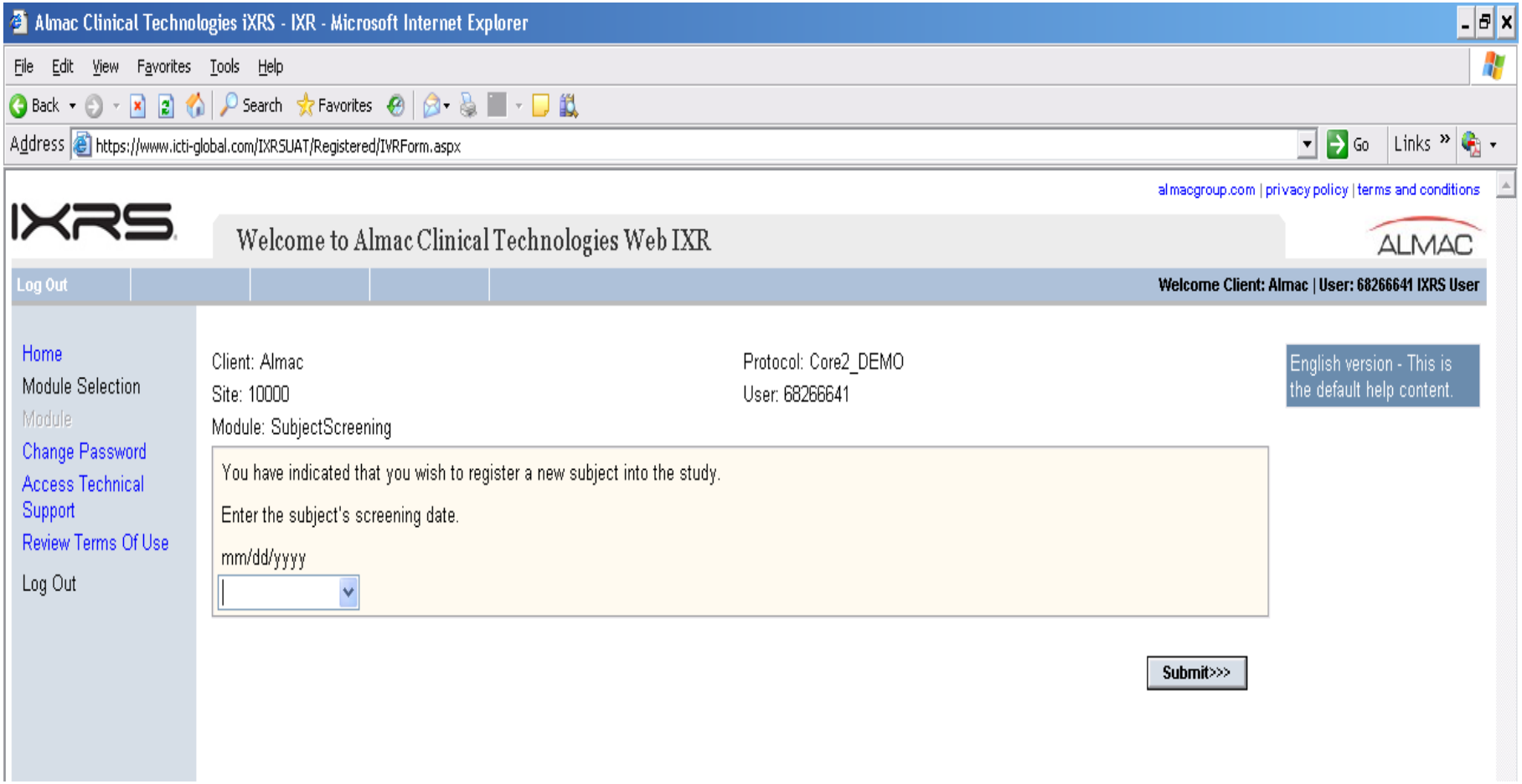


Emergency Un-blinding will be included for Investigator

Participant Screening

Note: this is just a sample, not study specific

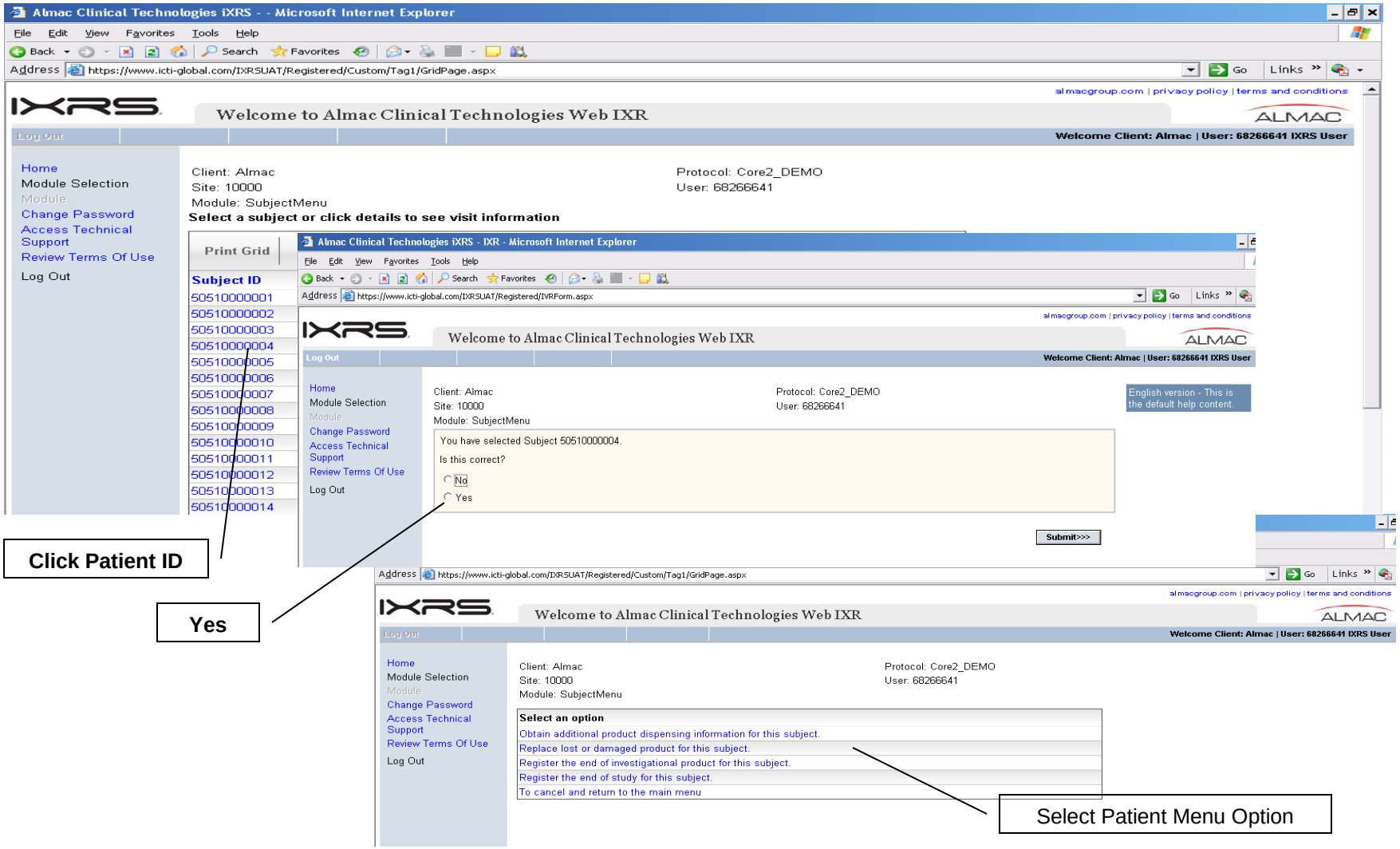
After clicking Register a new participant into study….



Activities Related to Participant

Note: this is just a sample, not study specific

After clicking Activities related to participant….



Click Patient ID

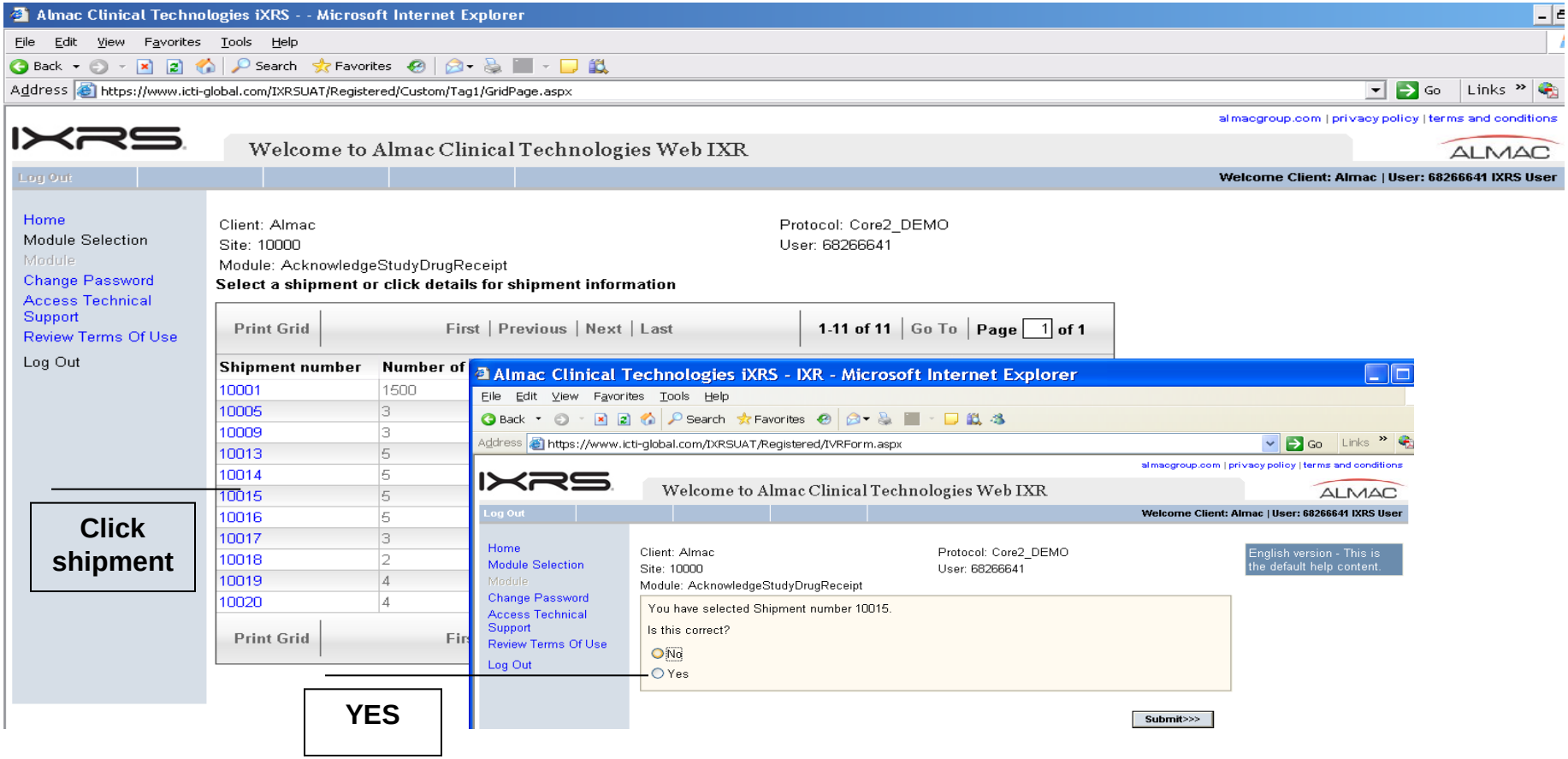
Yes

Select Patient Menu Option

Confirm Receipt of Product

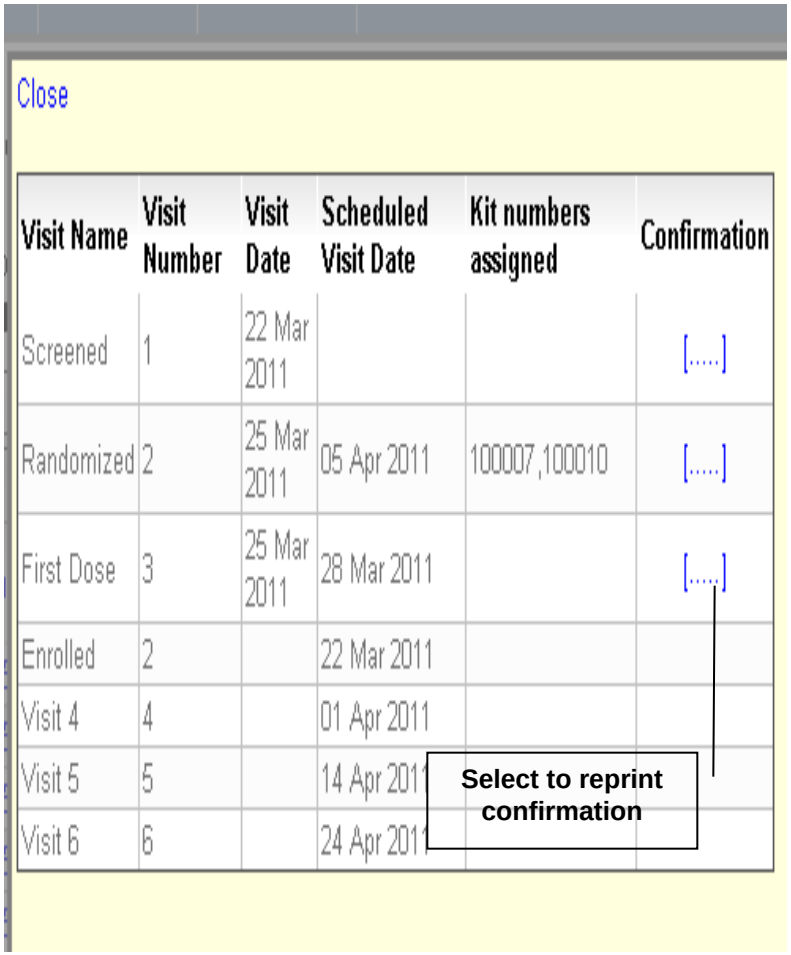
Note: this is just a sample, not study specific

After clicking Confirm Receipt of Product….



Confirmation Emails / Faxes

- After successful completion of IXRS® transaction, the system user or caller will receive either a confirmation email or fax
- These confirmations contain the key details from the registered event.
- If a correction is required, a line should be drawn through the error, the correct data written in, signed, dated and faxed to Almac 267-757-0411 or 44 28 3835 2122 or email IVRSSupport@almacgroup.com. (see sample next page)
- The project team will update the database accordingly and an amended fax/email will be sent to caller or system user.
- If confirmation has not been received, please revisit web to reprint. (see picture)



IXRS® Transaction (Sample Fax)

International Partnership for Microbicides
Protocol: IPM027
Randomization Confirmation

Local Date and Time of Transaction:
UTC Date and Time of Transaction:

Country: United States
Research Center: Unique ID
Investigator: Full Name
User: 8-digit user ID
User Type: Role
User Email: test.test@almacgroup.com

Participant ID: Unique ID
Date of Birth: ~~06/27/1972~~ **6/25/1972**
Product Allocated: XXXXX

Provider Name: ALMAC
Project Reference: IPM027

If any information contained in this fax/email is incorrect please strike-through incorrect data, record the correct data next to the incorrect data, sign and date below and fax the corrected form to: 267-757-0411 or 44 28 3835 2122

_____

Sign Here ***Date Here***

Signature Print Name Date

Technical Support

Almac provides 24 hour technical support; 365 days a year. Offices are based in UK and USA

Users can connect through the phone by entering the 6-digit study code *and* pressing 0 for Technical Support 1-877-738-8831 or IVRSSupport@almacgroup.com

If the call is:

- During business hours, you will be connected to your project team member
- After normal business hours and the call is urgent, the Project Manager will be paged to provide assistance
- After normal business hours and your call is not urgent, the technical support center will either resolve the issue or take a message and forward it to the correct study team members.

Thank you!