



Alliance Protocol Updates

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ALLIANCE

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Objectives

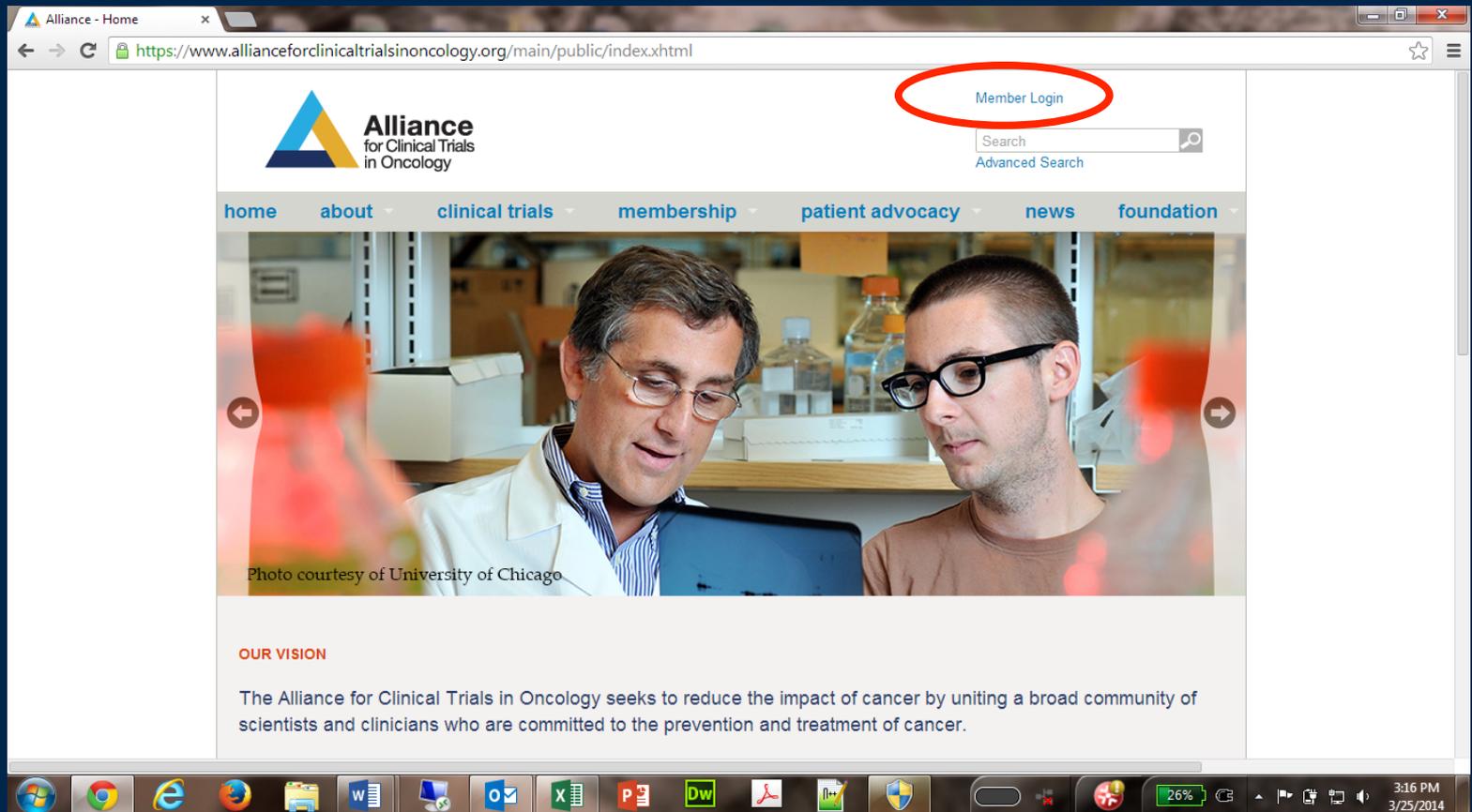
- Study Migration to the Alliance Web site
- Study Summaries on the Alliance Web site
- Protocol Contact Information
- Alliance Web site feedback

Study Migration to the Alliance Web site

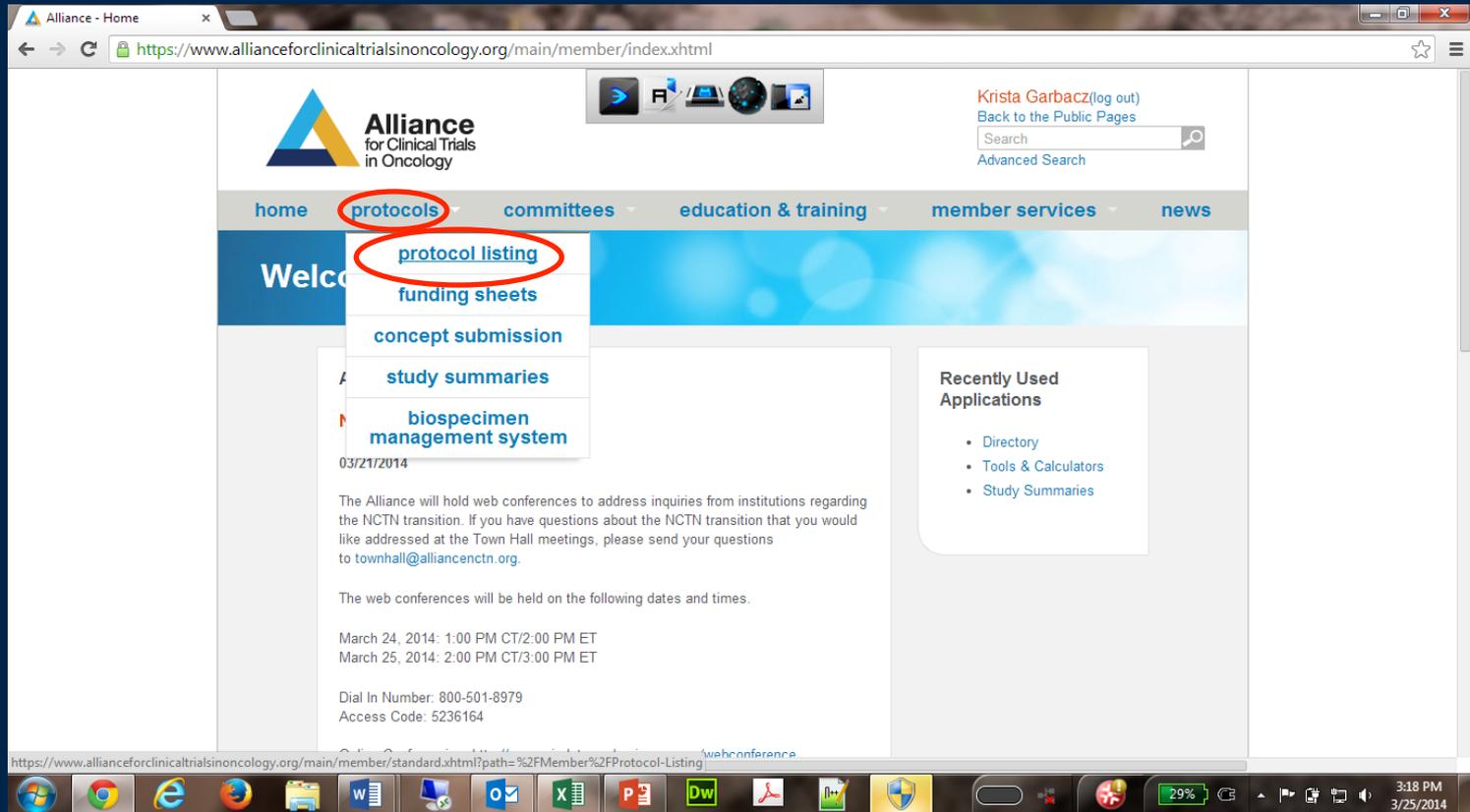
- All active Alliance and legacy ACOSOG, CALGB, NCCTG studies now posted
- Town Hall Meeting Presentation
- Next: Closed study migration

1. Sign onto the **member** side of www.allianceforclinicaltrialsinoncology.org

Note: You will use your CTEP IAM Username and password



2. Protocols are found under the protocols tab - protocol listing.



The screenshot shows a web browser window with the URL <https://www.allianceforclinicaltrialsinoncology.org/main/member/index.xhtml>. The page features the Alliance for Clinical Trials in Oncology logo and a navigation menu. The 'protocols' menu is open, and 'protocol listing' is highlighted with a red circle. Other menu items include 'home', 'committees', 'education & training', 'member services', and 'news'. The 'protocol listing' dropdown menu contains the following items: 'protocol listing', 'funding sheets', 'concept submission', 'study summaries', and 'biospecimen management system'. The main content area displays a welcome message and information about web conferences, including dates (March 24 and 25, 2014) and contact information (Dial In Number: 800-501-8979, Access Code: 5236164). A 'Recently Used Applications' sidebar lists 'Directory', 'Tools & Calculators', and 'Study Summaries'. The browser's taskbar at the bottom shows various application icons and the system clock indicating 3:18 PM on 3/25/2014.

3. Choose the committee from the Protocol Listing.

Protocol Listing

Home > Protocol Listing

PROTOCOL LISTING

The Alliance Protocol Listing is a list of ongoing Alliance legacy group protocols by committee, availability to members through the NCI's Cancer Trials Support Unit (CTSU), and implementation on the OPEN Registration System.

Disease

- Breast
- Gastrointestinal (GI)
- Genitourinary (GU)
- Leukemia
- Leukemia Correlative Science (LCSC)
- Lymphoma
- Myeloma
- Neuro-Oncology
- Respiratory
- Transplant

Modality and Discipline

- Cancer Control
- Experimental Therapeutics

Protocol Landing Page

Basic study information including: Title, Study Chair (hyperlinked to allow an email to be sent directly to the Study Chair), Activation Date, Study Status, Protocol Document, Model Informed Consent Document (word and pdf)

The screenshot displays a web browser window with the URL <https://www.allianceforclinicaltrialsinoncology.org/main/member/apps/protocols/protocol.xhtml?protocolPath=Leukemia%2FA041202%2FLanding>. The page features a navigation menu with links for home, protocols, committees, education & training, member services, and news. The main content area is titled "A041202" and includes a breadcrumb trail: Home > Protocol Listing > Leukemia > A041202. A sidebar on the left contains a list of links, with "A041202" circled in red. The main content area displays the following information:

- Alliance A041202**
- Title:** A Randomized Phase III Study of Bendamustine Plus Rituximab Versus Ibrutinib Plus Rituximab Versus Ibrutinib Alone in Untreated Older Patients (≥ 65 Years of Age) with Chronic Lymphocytic Leukemia (CLL)
- Study Chair:** Jennifer Woyach, MD
- Activation Date:** 12/09/2013
- Status:** Active
- Links:** A041202 Protocol Document - 12/09/2013; A041202 Model Consent (word) or (pdf) - 12/09/2013

At the bottom of the page, there are links for legacy sites, directory, newsletter & publications, meetings, wiki, and site map. The Windows taskbar at the bottom shows the system time as 3:19 PM on 3/25/2014 and a battery level of 31%.

All Documents

List of all documents found under each tab

Home > Protocol Listing > Leukemia > A041202 > All Documents

A041202

- A041202-00.pdf
- A041202-MCF-00.docx
- A041202-MCF-00.pdf

Updates and Action Letters

- A041202-ActivationNotice.pdf
- A041202-PreActivationNotice.pdf

Case Report Forms

- A041202 AllFormsPacket.pdf
- A041202-Step0-OPEN-EnrollmentForm-03122014.pdf
- A041202-Step1OPEN-EnrollmentForm-03122014.pdf

Memoranda

- A041202-AllianceActivationPolicy.pdf
- A041202-Revised Geriatric Assessment Forms and Booklet Ordering.pdf

Supplemental Materials

- A041202 Geriatric Assessment-Healthcare Professional Questionnaire.pdf
- A041202 Geriatric Assessment-Patient Questionnaire.pdf
- A041202-InitialAuditWksht.pdf

DSMB Statement and Study Summary

- A041202 StudySummary.pdf

Updates and Action Letters

Comprehensive list of all updates and action letters that have been released. Also included are the pre-activation notice (if applicable) and the activation notice.

The screenshot shows a web browser window with the URL <https://www.allianceforclinicaltrialsinoncology.org/main/member/apps/protocols/protocol.xhtml?path=%2FMember%2FProtocol-Listing%2FLeukemia%2FA041202%2FU>. The page header includes the Alliance logo and navigation links: home, protocols, committees, education & training, member services, and news. The main content area is titled 'A041202' and contains a breadcrumb trail: Home > Protocol Listing > Leukemia > A041202 > Updates and Action Letters. Below this, the section 'Updates & Action Letters' lists two items: 'A041202 Activation Notice - 12/09/2013' and 'A041202 Pre-Activation Notice - 10/22/2013'. A left sidebar menu is visible, with 'Updates and Action Letters' highlighted by a red circle. The Windows taskbar at the bottom shows the time as 3:21 PM on 3/25/2014.



Case Report Forms

Case Report Form documents found here. Most studies now use RAVE, but a pdf of the all forms packet is available. If we have a data submission schedule it would also be here. For legacy studies there may be a more extensive list of individual forms.

The screenshot shows a web browser window with the URL <https://www.allianceforclinicaltrialsinoncology.org/main/member/apps/protocols/protocol.html?path=%2FMember%2FProtocol-Listing%2FLeukemia%2FA041202%2FFo>. The page features the Alliance for Clinical Trials in Oncology logo and a navigation menu with links for home, protocols, committees, education & training, member services, and news. The main content area is titled "A041202" and includes a breadcrumb trail: Home > Protocol Listing > Leukemia > A041202 > Case Report Forms. A section titled "Case Report Forms" contains a list of documents:

- A041202 All Forms Packet - 12/09/2013
- A041202 Step 0 Open Enrollment Form - 03/12/2014
- A041202 Step 1 Open Enrollment Form - 03/12/2014

A sidebar on the left lists various document categories, with "Case Report Forms" circled in red. Other categories include All Documents, Updates and Action Letters, Memoranda, Supplemental Materials, DSMB Statement and Study Summary, and Drug Safety Notifications. The top right corner shows a user profile for Krista Garbacz (log out) and a search bar. The bottom of the image shows a Windows taskbar with various application icons and a system tray displaying the time as 3:21 PM on 3/25/2014.



Memoranda (soon will be re-named Memoranda and Broadcasts)

All memoranda associated with a study can be found here. Under the broadcast heading you will find any study broadcast messages concerning the study that have been sent.

The screenshot shows a web browser window displaying the Alliance for Clinical Trials in Oncology website. The URL is <https://www.allianceforclinicaltrialsinoncology.org/main/member/apps/protocols/protocol.xhtml?path=%2FMember%2FProtocol-Listing%2FETC%2FA091105%2FMemo&>. The page title is "Alliance A091105". The navigation menu includes "home", "protocols", "committees", "education & training", "member services", and "news". The search bar shows "Krista Garbacz(log out)" and "Back to the Public Pages". The main content area is titled "Alliance A091105" and includes a breadcrumb trail: "Home > Protocol Listing > Experimental Therapeutics > Alliance A091105 > Memoranda". The "Memoranda" section is circled in red and contains a list of documents: "Memorandum Re: New Protocol Activation Definitions and Procedures - 03/15/2013". The "Broadcasts" section contains a list of documents: "Broadcast: A091105 StudyActivation and N1153-Status Change Notice - 03/21/2014". The footer includes "legacy sites", "directory", "newsletter & publications", "meetings", "wiki", and "site map". The system tray shows the date and time as 3:22 PM on 3/25/2014.



Supplemental Materials

Any study related documents not found on another tab may be found here. Examples include: Audit worksheets, Drug Order Forms, Questionnaires

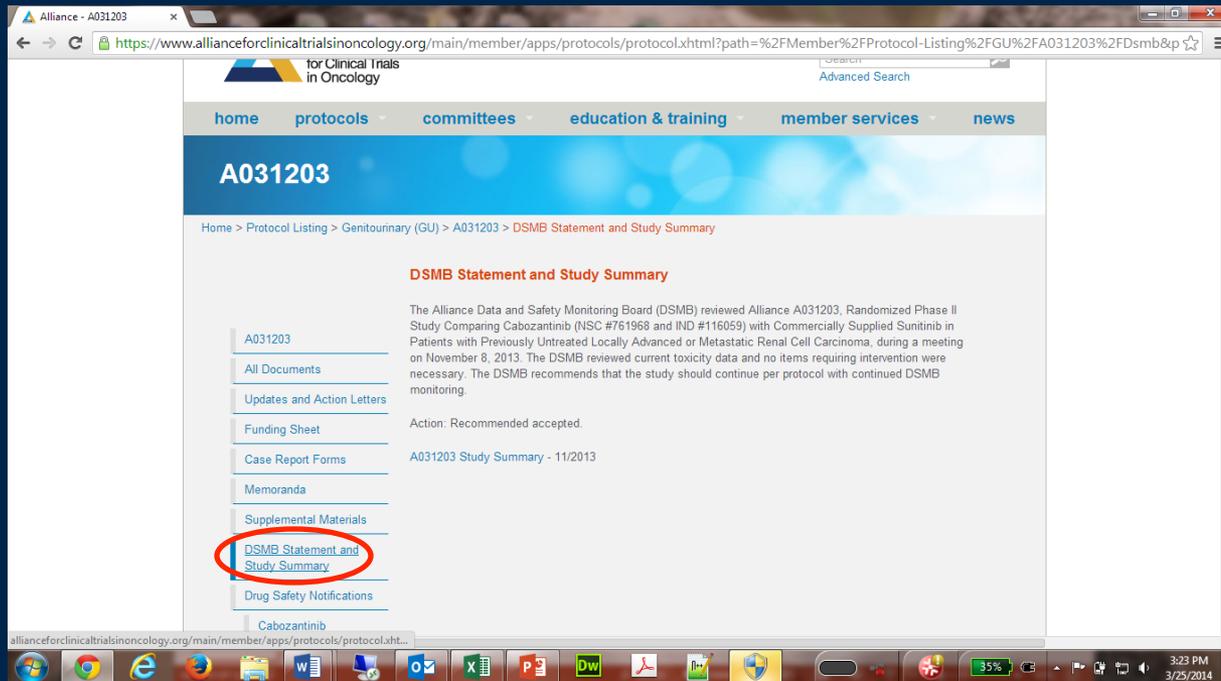
The screenshot shows a web browser window with the URL <https://www.allianceforclinicaltrialsinoncology.org/main/member/apps/protocols/protocol.html?path=%2FMember%2FProtocol-Listing%2FLeukemia%2FA041202%2FSu>. The page features the Alliance for Clinical Trials in Oncology logo and navigation tabs: home, protocols, committees, education & training, member services, and news. The main content area is titled 'A041202' and includes a breadcrumb trail: Home > Protocol Listing > Leukemia > A041202 > Supplemental Materials. A sidebar on the left contains a list of links: All Documents, Updates and Action Letters, Case Report Forms, Memoranda, Supplemental Materials (circled in red), DSMB Statement and Study Summary, and Drug Safety Notifications. The main content area is titled 'Supplemental Materials' and lists three items: A041202 Geriatric Assessment: Patient Questionnaire - 11/25/2013, A041202 Geriatric Assessment: Healthcare Professional Questionnaire - 11/05/2013, and A041202 Initial Audit Worksheet. The browser's taskbar at the bottom shows various application icons and the system clock indicating 3:22 PM on 3/25/2014.



DSMB Statement and Study Summary

If the study is monitored by the DSMB (all Phase III and any Randomized Phase II studies) the DSMB statement and Recommended Action from the last DSMB meeting will be posted here.

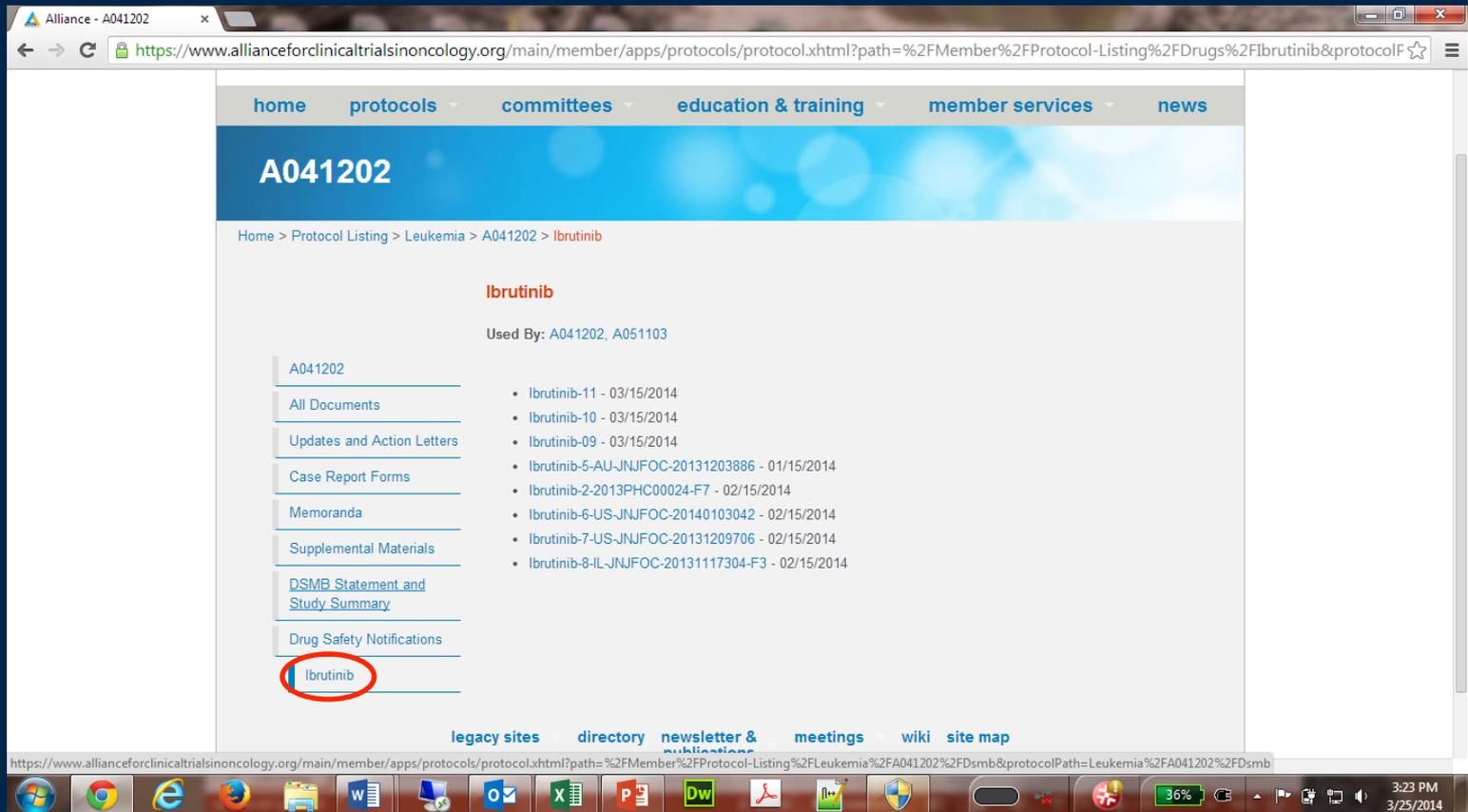
The latest study summary can also be found here. If the study was not activated at the time of the last meeting you will not find a study summary until the next meeting.



The screenshot shows a web browser window displaying the Alliance for Clinical Trials in Oncology website. The URL is <https://www.allianceforclinicaltrialsinoncology.org/main/member/apps/protocols/protocol.xhtml?path=%2FMember%2FProtocol-Listing%2FGU%2FA031203%2FDsmb&p>. The page title is "A031203". The navigation menu includes "home", "protocols", "committees", "education & training", "member services", and "news". The main content area is titled "A031203" and contains a breadcrumb trail: "Home > Protocol Listing > Genitourinary (GU) > A031203 > DSMB Statement and Study Summary". The section is titled "DSMB Statement and Study Summary". The text states: "The Alliance Data and Safety Monitoring Board (DSMB) reviewed Alliance A031203, Randomized Phase II Study Comparing Cabozantinib (NSC #761968 and IND #116059) with Commercially Supplied Sunitinib in Patients with Previously Untreated Locally Advanced or Metastatic Renal Cell Carcinoma, during a meeting on November 8, 2013. The DSMB reviewed current toxicity data and no items requiring intervention were necessary. The DSMB recommends that the study should continue per protocol with continued DSMB monitoring." The "Action" is "Recommended accepted." The "A031203 Study Summary - 11/2013" is also listed. A sidebar on the left contains a list of links: "A031203", "All Documents", "Updates and Action Letters", "Funding Sheet", "Case Report Forms", "Memoranda", "Supplemental Materials", "DSMB Statement and Study Summary" (circled in red), and "Drug Safety Notifications". The bottom of the page shows the Alliance for Clinical Trials in Oncology logo and the text "Alliance for Clinical Trials in Oncology". The Windows taskbar at the bottom shows the date and time as 3:23 PM on 3/25/2014.

Drug Safety Notifications

If the study has a drug that has safety notifications the name of the drug will be listed under the heading of Drug Safety Notifications. **Note:** You have to click on the name of the drug to be directed to the drug page. When you navigate to the drug page there will be a list of all the studies using the drug listed under the drug name.



The screenshot shows a web browser window displaying the Alliance for Clinical Trials in Oncology website. The URL is <https://www.allianceforclinicaltrialsinoncology.org/main/member/apps/protocols/protocol.html?path=%2FMember%2FProtocol-Listing%2FDrugs%2FIbrutinib&protocolF>. The page title is "A041202". The breadcrumb trail is "Home > Protocol Listing > Leukemia > A041202 > Ibrutinib". The main heading is "Ibrutinib". Below it, it says "Used By: A041202, A051103". There is a list of studies using Ibrutinib:

- Ibrutinib-11 - 03/15/2014
- Ibrutinib-10 - 03/15/2014
- Ibrutinib-09 - 03/15/2014
- Ibrutinib-5-AU-JNJFOC-20131203886 - 01/15/2014
- Ibrutinib-2-2013PHC00024-F7 - 02/15/2014
- Ibrutinib-6-US-JNJFOC-20140103042 - 02/15/2014
- Ibrutinib-7-US-JNJFOC-20131209706 - 02/15/2014
- Ibrutinib-8-IL-JNJFOC-20131117304-F3 - 02/15/2014

On the left side, there is a sidebar with a menu. The "Drug Safety Notifications" section is expanded, and the "Ibrutinib" link is circled in red.

At the bottom of the page, there are links for "legacy sites", "directory", "newsletter & publications", "meetings", "wiki", and "site map". The taskbar at the bottom shows the Windows Start button, several application icons, and the system tray with the date and time "3:23 PM 3/25/2014".

Study Summaries (by Committee) on the Alliance Web site

The screenshot shows the Alliance for Clinical Trials in Oncology website. The browser address bar displays the URL: <https://www.allianceforclinicaltrialsinoncology.org/main/member/standard.xhtml?path=%2FMember%2FStudy-Summaries>. The page header includes the Alliance logo, navigation links (home, protocols, committees, education & training, member services, news), and a user profile for Krista Garbacz. A dropdown menu is open under 'Study', with 'study summaries' highlighted by a red circle. Below the menu, the page content includes a description of study summaries, a last updated date of 11/01/2013, and lists of diseases and modalities.

Alliance for Clinical Trials in Oncology

Krista Garbacz(log out)
Back to the Public Pages

Search
Advanced Search

home protocols committees education & training member services news

Study
protocol listing
funding sheets
concept submission
study summaries
biospecimen management system

Home > Study Summaries

Study summaries contain interim reports for Alliance studies that contain toxicity summaries. Study summaries may be included among these reports. The summaries and concepts are privileged information and are not for publication or reference. They may be downloaded from the list below.

Last updated 11/01/2013

Disease

- Breast
- Gastrointestinal (GI)
- Genitourinary (GU)
- Leukemia
- Leukemia Correlative Science
- Lymphoma
- Melanoma
- Myeloma
- Neuro-Oncology
- Respiratory

Modality and Discipline

- Cancer Control
- Experimental Therapeutics
- Imaging
- Pharmacogenomics and Population Pharmacology
- Transplant

Individual Study Summaries on the Alliance Web Site

The screenshot shows a web browser window with the URL <https://www.allianceforclinicaltrialsinoncology.org/main/member/apps/protocols/protocol.xhtml?path=%2FMember%2FProtocol-Listing%2FBreast%2FA011106%2FDsmb&protocolPath=Breast%2FA011106%2FDsmb>. The page features the Alliance logo and navigation menu. The breadcrumb trail [Home](#) > [Protocol Listing](#) > [Breast](#) > [Alliance A011106](#) > [DSMB Statement and Study Summary](#) is circled in red. Below the breadcrumb, the page title is **DSMB Statement and Study Summary**. A sidebar menu lists various documents, with [DSMB Statement and Study Summary](#) circled in red. At the bottom, there are links for [legacy sites](#), [directory](#), [newsletter & publications](#), [meetings](#), [wiki](#), and [site map](#). A footer link reads [Questions or Issues? Contact Us](#).

Alliance Web site feedback

- Send an email to:
transition@alliancencn.org
- Fill out the Web site survey
<https://surveymonkey.com/s/AllianceWebsite>



Protocol Contact Info

Alliance Protocol Numbers and Protocol Coordinators

Protocol numbers are assigned by the Alliance database prior to concept review. The first character of the protocol number is an A, followed by two digits representing the committee; the next two digits indicate the year the concept was introduced; and the final two digits are assigned consecutively as concepts are submitted. For example, the first Breast concept in 2013 is protocol A011301. The following table lists the committees, and their protocol number format and assigned Protocol Coordinator.

	Protocol Number	Protocol Coordinator	Email	Phone
Disease Committees				
Breast	A01YYXX	Heather Becker	hpbecker@uchicago.edu	773-834-2546
Gastrointestinal	A02YYXX	Vance Erese	verese@uchicago.edu	773-834-4518
Genitourinary	A03YYXX	Michele Seiler	msexton@uchicago.edu	773-834-4014
Leukemia	A04YYXX	Samantha Sublett	ssublett@uchicago.edu	773-834-4091
Lymphoma	A05YYXX	Guadalupe Aquino	gaquino@uchicago.edu	773-702-4236
Myeloma	A06YYXX	Guadalupe Aquino	gaquino@uchicago.edu	773-702-0956
Neuro-Oncology	A07YYXX	Tamara Robles	roblest@uchicago.edu	773-702-9902
Respiratory	A08YYXX	Colleen Watt	cboyle@uchicago.edu	773-702-4670
Scientific Discipline Committees				
Experimental Therapeutics	A09YYXX	Aimee Farrell	afarrell1@uchicago.edu	773-702-0893
Imaging	A10YYXX	Guadalupe Aquino	gaquino@uchicago.edu	773-702-0956
Leukemia Correlative Sciences	A11YYXX	Samantha Sublett	ssublett@uchicago.edu	773-834-4091
Pathology	A12YYXX	Aimee Farrell	afarrell1@uchicago.edu	773-702-0893
Pharmacogenomics & Population Pharmacology	A02YYXX	Vance Erese	verese@uchicago.edu	773-834-4518
Radiation Oncology	A03YYXX	Michele Seiler	msexton@uchicago.edu	773-834-4014
Correlative Sciences	A15YYXX	Please contact the assigned Protocol Coordinator for the Disease Committees.		
Transplant	A16YYXX	Guadalupe Aquino	gaquino@uchicago.edu	773-702-0956
Cancer Control Committees				
Cancer in the Elderly	A17YYXX	Kimberly Thomas	kthoma16@uchicago.edu	773-702-8824
Health Disparities	A19YYXX	John Taylor	jtaylor1@uchicago.edu	773-702-1767
Health Outcomes	A20YYXX	John Taylor	jtaylor1@uchicago.edu	773-702-1767
Prevention	A21YYXX	John Taylor	jtaylor1@uchicago.edu	773-702-1767
Symptom Intervention	A22YYXX	Kimberly Thomas	kthoma16@uchicago.edu	773-702-8824
ACS Clinical Research Committees				
Cancer Care Delivery Research	A23YYXX	Please contact Krista Garbacz for the assigned Protocol Coordinator.		
Additional Protocol Staff				
Director, Protocol Operations		Mike Kelly	mkelly1@uchicago.edu	773-702-8812
Associate Director, Protocol Operations		Morgen Alexander-Young	malexanderyoung@uchicago.edu	773-702-4236
Protocol Information Specialist		Krista Garbacz	kgarbacz@uchicago.edu	773-702-9269

Revised 05/01/2014

AE Questions

- Contact Regulatory Affairs Manager by phone: **773-702-9814**
- Send an email to the regulatory in-box **regulatory@alliancencctn.org**

Questions?

