



# Alliance Bi-Monthly Protocol Status Sheet

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# Alliance Status Sheet

- Generated by Alliance Central Protocol Operations Program on a bi-monthly basis since Alliance inception (monthly w/in legacy CALGB)
- Complete listing of Alliance active and in-development trials
  - In-development trials listed by Alliance disease committee with status and development stage
    - SCRC = new concept without NCI concept approval
    - C = concept for proposal with > 100 patients
    - P = protocol
    - LOI = letter of intent for proposals with < 100 patients
    - NCI = under NCI CTEP review
    - DCP = under NCI DCP review
    - CIRB = under NCI CIRB review
    - PO = at Alliance Protocol Operations
  - P/po = protocol at Alliance Protocol Operations; LOI/NCI = letter of intent under NCI review; C/NCI = concept under NCI review; P/CIRB = protocol under CIRB review
- Available on the Alliance web site Protocols > Protocol Listing > Additional Resources > Status Sheet

# Protocols and Concepts in Development

## LEUKEMIA COMMITTEE

A041701	P/CIRB	Older AML intensive chemo (7+3) +/- GMI-1271	II/III	G. Uy
A041702	P/CIRB	Ibrutinib vs ibrutinib+venetoclax+obinutuzumab in older CLL pts	III	J. Woyach
A041703	P/po	Inotuzumab + blinatumomab for pts w/ CD22+ B-lineage ALL	II	M. Wieduwilt

## LYMPHOMA COMMITTEE

A051701	P/po	Venetoclax + dose-adjusted EPOCH-R for MYC/BCL2 DHL & DPL	II/III	J. Abramson
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## MYELOMA COMMITTEE

A061802	SCRC	Lenalidomide vs lenalidomide + citarinstat as maintenance tx following ASCT for myeloma	II	S. Holstein
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## NEURO-ONCOLOGY COMMITTEE

A071701	P/po	Genomically-guided trial in brain metastases	II	P. Brastianos
A071702	SCRC	Checkpoint blockade immunotherapy in pts w/ somatically hypermutated GBM	II	G. Dunn
A071801	P/po	Single fraction SRS vs fractionated SRS for resected brain mets	III	P. Brown

NCI - CTEP Review   DCP - Division of Cancer Prevention   CIRB - Central IRB   po - Protocol Office  
 C - Concept   LOI - Letter of Intent   P - Protocol   SCRC - Study Concept Review Committee Approved   PA - Pre-Activation

# Active Protocols

- Complete listing of Alliance active and in-development trials
  - Active trials listed by Alliance disease committee with activation date, phase, study chair, and most current update/addendum (eg, Update 7 to A01104, Update 8 to A011202,etc.)

## ACTIVE PROTOCOLS - November 1, 2018

<u>Number</u>	<u>Study Short Title</u>	<u>Phase</u>	<u>Study Chair</u>	<u>Activated</u>
<b><u>BREAST COMMITTEE</u></b>				
A011104-07	Preop Br MRI on surg outcomes, costs, and QOL of women w/BrCa	III	I. Bedrosian	02/21/14
A011202-08	Eval of axill LN dissect in BrCa pts w/+ SLN Dz post neoadj chemo	III	J. Boughey	02/07/14
A011401-03	Role of weight loss in adj tx	III	J. Ligibel	08/29/16
A011502-04	Asprin adj tx node+	III	W. Chen	12/08/16
CTSU	S1207: Rand plcb cont end tx +/- everolimus HR+ HER2- br ca	III	M. Goetz	09/03/13
CTSU	S1416: Cisplatin +/- veliparib in met triple-neg / BRCA breast ca	II	C. Anders	07/07/16
<b><u>CANCER CARE DELIVERY RESEARCH</u></b>				
A191402CD-04	Decision aids for minority prostate ca pts	III	J. Tilbert	07/14/17
CTSU	S1415CD: TRACER		G. Chang	10/07/16

## CANCER IN THE OLDER ADULT

# Recent Activations, Suspensions and Closures

## RECENT PROTOCOL ACTIVATIONS

(in order of activation date)

<u>Number</u>	<u>Study Short Title</u>	<u>Study Chair</u>	<u>Activated</u>
A091605-03	Stereotactic body radiotherapy + anti-PD1 antibody in adv Merkel cell ca	J. Luke	02/01/18
A221505-00	Hypofractionated post mastectomy rad w/ breast reconstruct	M. Poppe	02/01/18
A021602-00	Cabozantinib vs placebo in pts w/ adv neuroendocrine tumor	J. Chan	07/18/18
A031701-00	Dose-dense gemcitabine in muscle-invasive bladder ca pts	G. Iyer	08/01/18
A211601-00	Comp to A011502: Eval of mammographic breast density effect of aspirin	M. Wood	08/01/18
A171601-00	Palbociclib w/ letrozole or fulvestrant in pts 70+ w/ HR+, HER2-neg breast ca	A. Hurria	08/15/18
A211701-00	A prospective study to establish a new onset diabetes cohort	S. Chari	10/15/18
A221602-00	Olanzapine +/- fosaprepitant for prevention of CINV in pts receiving HEC	R. Navari	10/15/18

## CURRENT PROTOCOL SUSPENSIONS

(in order of suspension date)

<u>Number</u>	<u>Study Short Title</u>	<u>Study Chair</u>	<u>Activated</u>	<u>Suspended</u>
A071401-07	SMO/AKT/NF2 prg meningiomas	P. Brastianos	08/28/15	02/07/18
CTSUS	NRG-GI002: Clinical trial platform of sensitization utilizing (TNT) in rectal	O. Rahma	10/12/16	02/12/18
A021501-03	PreOp extend chemo vs chemo + hypofrac RT borderline pancreatic ca	M. Katz	12/01/16	05/09/18
A051301-05	Ibrutinib DLBCL	C. Babis Andreadis	07/06/16	08/24/18
A091401-09	Nivolumab +/- ipilimumab	S. D'Angelo	07/30/15	09/05/18
A011106-06	Alt approaches clin stg II & III ER+ BrCa (ALTERNATE)	C. Ma	12/13/13	11/01/18

## RECENT PROTOCOL CLOSURES

(in order of closure date)

<u>Number</u>	<u>Study Short Title</u>	<u>Study Chair</u>	<u>Activated</u>	<u>Closed</u>
A221102-06	Testosterone for arthralgia	C. Loprinzi	09/07/12	12/01/17
N1153-01	Sorafenib, TH-302	M. Borad	05/11/12	12/01/17
CTSUS	S1513: Rand ph II 2nd line FOLFIRI v mFOLFIRI w/ ABT-888 in met pan ca	M. Pishvaian	09/01/16	12/13/17