Trial Acronym	P.I.	Study Title	IRB No.	Title of IND or Name of Device	Revised Investigational Component 1	Investigational Component 2	Current Reg Status/Action Items	Questions	clinicaltrials.gov	Disease sub-type
GBOP0701	Marcom	A Randomized Phase II Trial Evaluating the Performance of Genomic Expression Profiles to Direct the Use of Preoperative Chemotherapy for Early Stage Breast Cancer	pro00001345	AC=doxorubicin and cyclophosphamide or TC=docetaxel and cyclophosphamide in early breast	Possible new indication. TC is not approved as a dual therapy. Doc (T) is only approved as monotherapy or as triple therapy in combination with Dox and Cyclo. Further, this approval is for late stage and not early stage.	Genomic Guided between standard of care	IND exemption status should be addressed. IDE?	Need to be assessed as IDE?	NCT00636441	breast
PAN	Ready	Factor (EGFR) Pathway Signature Analysis Before and After Panitumumab Therapy in Untreated Locally Advanced Squamous Cell Cancer of the Head and Neck (SCCHN)	not yet submitted	Pan in Head and Neck	new indication.	None. All comers - gathering data	IND exemption status should be addressed.	Does Amgen want to hold an IND?	not yet submitted	head & neck
CALGB 30506	Harpole	A Randomized Phase III Trial to Evaluate the Capacity of a Genomic Prognostic Model to Identify Stage I NSCLC Patients as Candidates for Adjuvant Chemotherapy	pro00010529	Randomized to observation (standard of care) or Cis/Vis, Cis/Doc, Cis/Gem for lung	New indications. Vin approved for late stage lung not early stage; docetaxel approved for late stage lung not early.	Risk Recurrence - Genomic preditor of risk; multiple predictors (standard care is surgery then observation)	IND exemption status should be addressed. IDE?	IND? IDE? CALGB - check with contact. Are drugs entered properly into eIRB?	not yet submitted	lung
Dasatinib-advanced (TOP0801)	Kelley	Phase II Study of Dasatinib in Previously treated Patients with Advanced Non-small Cell Lung Cancer	pro00008303	Das used in lung - new indication	new indication for dasatinib IND letter on file.	Genomic Guided; single predictor (prediction in 2nd phase)	IND Exempt letter to Dr. Kelley on file	Is it OK to predict investigational therapy?	NCT00787267	lung
TOP0602	Potti formerly Garst	Phase II Prospective Study Evaluating the Role of Pemetrexed Plus Gemcitabine Chemotherapy for chemo naïve Select Stage IIIB and IV Non-Small Cell Lung Cancer (NSCLC) in Patients Using a Genomic Predictor of Platinum Resistance to Guide Therapy	pro00004599	Cis plus gem or pem plus gem - Choice based on Cis sensitivity	new combination of gem/pem.	Genomic guided; Multiple Predictors	IND exemption status should be addressed. IDE?	Does drug combination need evaluation for IND exemption. Need to be assessed as IDE?	NCT00509366	lung
TOP0703	Ready	Phase II Prospective study evaluating the Role of Directed Cisplatin based Chemotherapy with either Vinorelbine or Pemetrexed for the Adjuvant Treatment of Early Stage NSCLC in Patients Using genomic Expression Profiles of Chemotherapy Sensitivity to Guide Therapy	pro00000657	Cis/Pem or Cis/Vin - Choice based on	none	Genomic Guided; single predictor	IND exemption status should be addressed. IDE?	Need to be assessed as IDE?	NCT00545948	lung
TOP0706	Ready	Phase II Study Evaluating the Safety and Response to Neoadjuvant dasatinib in early stage Non-small Cell Lung Cancer (NSCLC)	pro00001278	Das used in lung - new indication (early stage)	new indication for dasatinib IND exemption letter on file.	None. No prediction - gathering data	IND exempt letter to Dr. Ready on file	None	NCT00564876	lung
everolimus	Ready	Phase II Study of Everolimus in Previously Treated Patients with Advanced Non-Small Cell Lung Cancer (NSCLC)	not yet submitted	Everolimus for lung	new indication.	None. All comers - gathering data	IND exemption status should be addressed.	Does Novartis want to hold an IND?	not yet submitted	lung
CALGB 30702	Ready	Genome-guided Chemotherapy for Advanced Stage Non-small Cell Lung Cancer: a Limited Institution, Randomized Phase II Study	not yet submitted	Randomized to genomic guided therapy consisting of two of the followinig: pem, gem, doc (or pac if with gem), and/or vin or cisplatin plus gemcitabine if cisplatin sensitive.	new combinations.	Genome guided; Multiple Predictors	IND exemption status should be addressed. IDE?	Does drug combination need evaluation for IND exemption. Need to be assessed as IDE?	not yet submitted	lung
MAD	Febbo	Assessment of the utility and efficacy of genomic profiles of chemosensitivity to individualize care for patients with metastatic cancer	not yet submitted	Multiple drugs using predictors	device concerns; potentially new indications (I didn't check on this yet)	Genomic guided; Multiple Predictors	IND exemption status should be addressed. IDE?	Need to be assessed as IDE?	not yet submitted	metastatic
Repository	Febbo	Specimen Repository for Genomic and Genetic Analyses in Cancer	pro000…	N/A	none	None	none	How are adverse events reported for screen failures to IRB to monitor safety if only consented to biorepository?	non-interventional	multiple
AR protocol	Febbo	A Phase II Trial of Genomic Guided Therapy with Dasatinib or Nilutamide in Metastatic Castration-Resistant Prostate Cancer	Pro00012159 (under review)	Das/Nil in prostate	new combination/indication for dasatinib. IND exemption letter on file	Genomic Guided; 2 predictors	IND Exemption to Dr. Febbo on file. IDE?	Need to be assessed as IDE?	not yet submitted	prostate
'Docetaxel Biopsy' (DBX)	Febbo	Prospective Validation of a Microarray-based Docetaxel Response Signature in Metastatic, Hormone-refractory Prostate Cancer	pro000…	N/A	none	None	o.k.	None	non-interventional	prostate

Note: new indication does not necessarily warrant an IND, off label is o.k. for an IRB approved research protocol, but review as such by IRB is critical. Key might be if predicting between standard of care or some other treatment.

Yes - new indication doesn't necessarily mean an IND is required. However, the question should be addressed by the investigator and IRB. This should be documented somewhere.