

The ClinicalTrials.gov Results Database as a Resource for Designing Clinical Trials

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Background

- Glomerular filtration rate (GFR), a measure of kidney function, is a primary or secondary outcome in many clinical trials.
- Power analysis for new trials requires estimates of both the difference between groups and the SD of GFR change.
- Estimates of SD are usually based on publications and/or unpublished data.
- The new ClinicalTrials.gov results database might serve as a source for estimates of this SD.

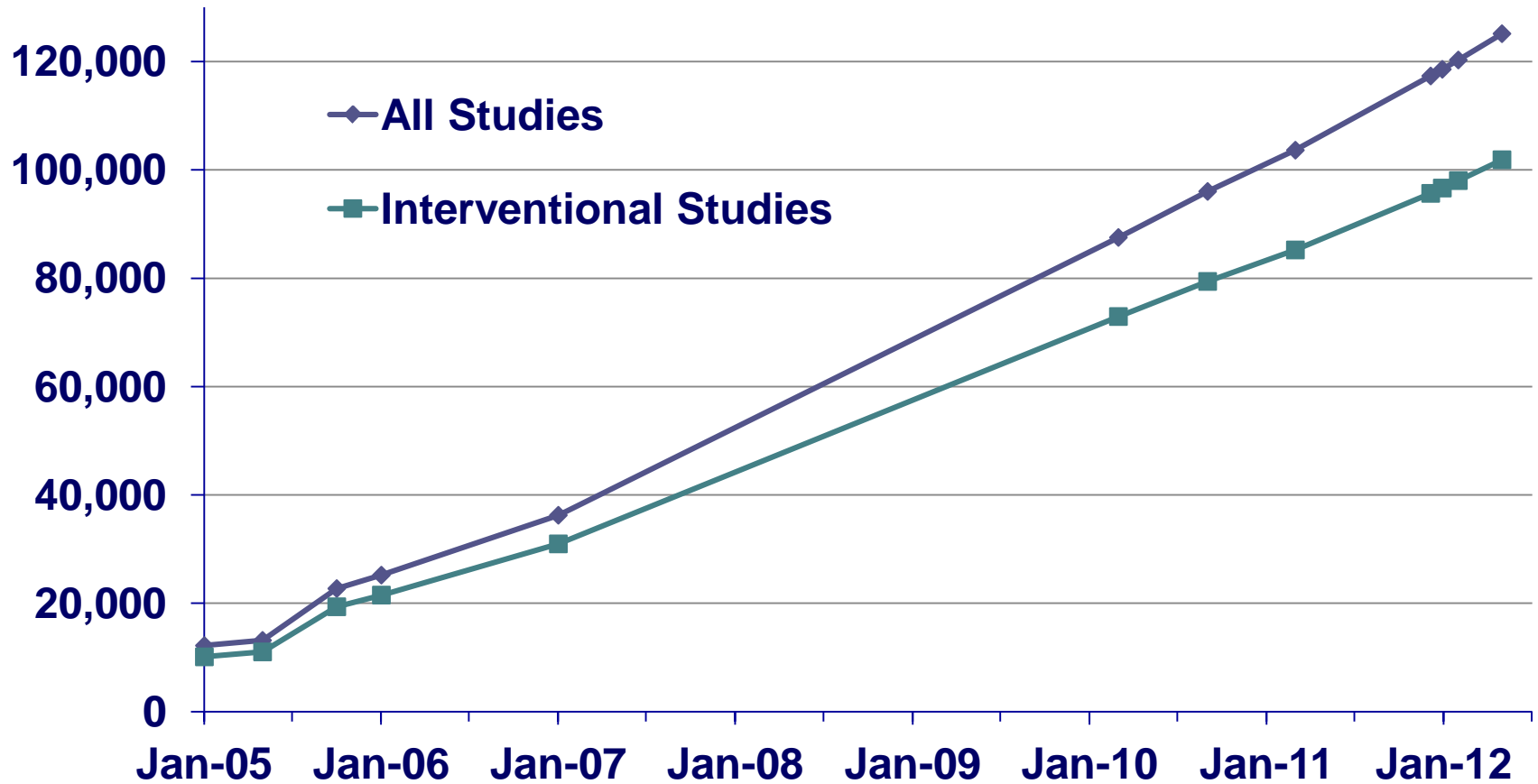
Purpose

- The purpose of this presentation is to answer the following:
 - Can relevant trials be easily identified on ClinicalTrials.gov?
 - What proportion of identified trials have results?
 - Are the results useful and understandable?
 - How many trials have been published?
 - Do the ClinicalTrials.gov results data agree with the publications?

ClinicalTrials.gov

- ClinicalTrials.gov (CTG) is a registry and results database of clinical trials.
- Mandated by Congress in 1997 and made available by NLM in 2000.
- Usage increased in 2005 when many journals required protocol registration for publication.
- In 2007 congress required that results be submitted for selected trials.
- CTG currently contains 126,112 trials conducted in 179 countries.

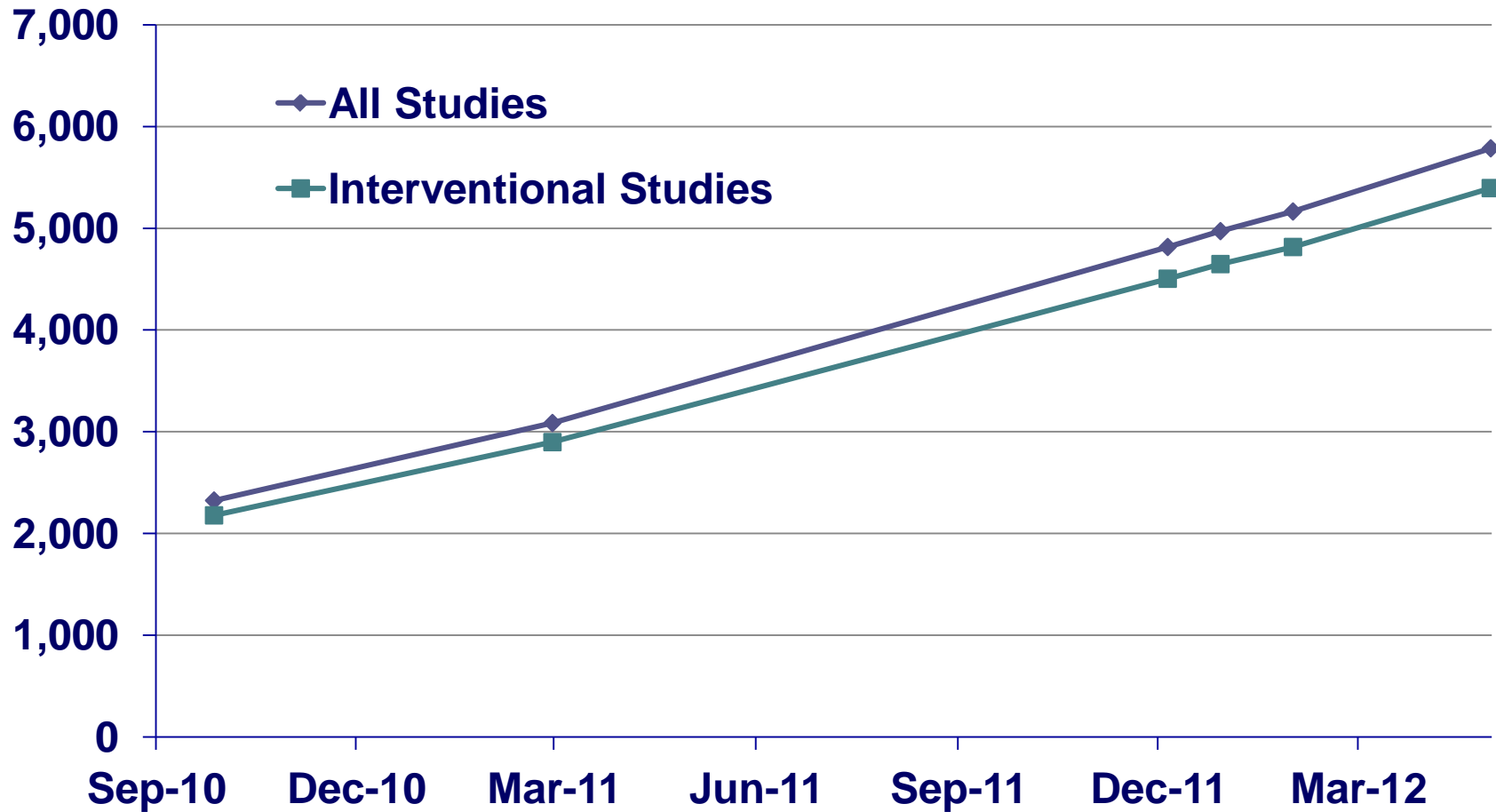
CTG Protocol Database



CTG Results Database

- Results should be posted within 1 year after completion of data collection for the primary outcome for trials that are:
 - Phase 2-4 intervention trials,
 - Drug, biologic, or device regulated by the FDA,
 - With at least one site in the U.S, and
 - Started after or ongoing as of 9/27/2007.
- Results may also be posted for trials not meeting these requirements.

CTG Results Database



Methods

- We performed a search on 11/10/2011 for trials with GFR as an outcome measure.
- Protocol descriptive data (20 fields) were downloaded from CTG as a text file.
- The text file was converted into a SAS® dataset that was used to select trials for further review.
- Individual CTG records were reviewed for further protocol information and results.
- PubMed was searched for publications for selected trials.

Search Example

[List Results](#)**Refine Search**[Results by Topic](#)[Results on Map](#)[Search Details](#)

Refine your search here or [Start Over](#).

Change your search with any or all of the fields below.
Search within your current results by adding more search terms.

[Search Terms:](#)

[Recruitment:](#) Exclude Unknown Status

[Study Results:](#)

[Study Type:](#)

[Help](#)

Targeted Search:

[Conditions:](#)

[Interventions:](#)

[Outcome Measures:](#)

Sample Protocol Information

<u>Condition</u>	<u>Intervention</u>	<u>Phase</u>
Kidney Diseases	Drug: Enteric-coated mycophenolate sodium (EC-MPS) Drug: Tacrolimus Drug: Corticosteroids	Phase 3

Study Type: Interventional

Study Design: Allocation: Randomized

Endpoint Classification: Safety/Efficacy Study

Intervention Model: Parallel Assignment

Masking: Open Label

Primary Purpose: Treatment

Sample Results

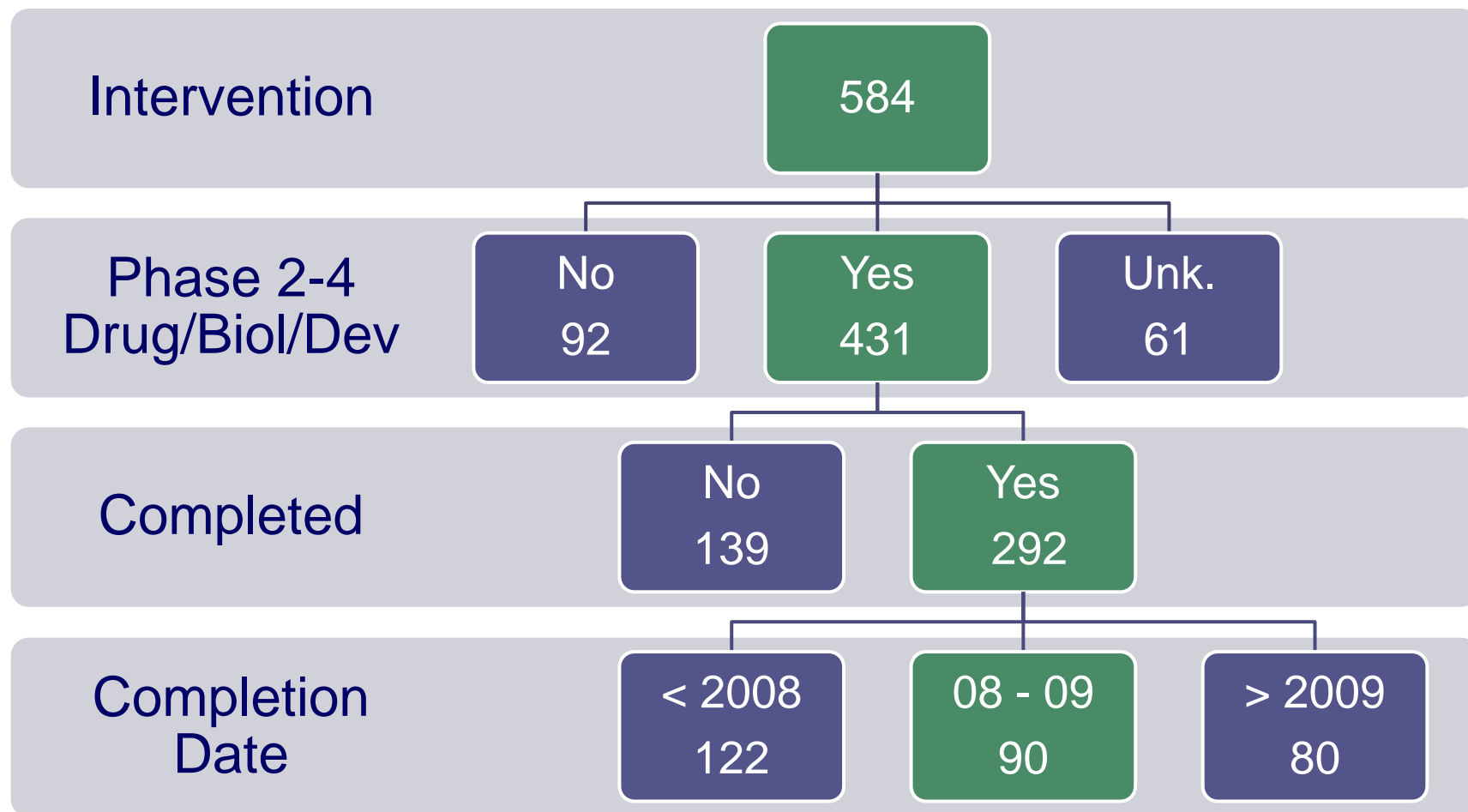
Measured Values

	Standard Dose EC-MPS	
Number of Participants Analyzed [units: participants]	47	
Renal Function Assessed by Change in Estimated Glomerular Filtration Rate(eGFR) [units: mL/min/1.73m ²] Mean ± Standard Deviation		
Baseline (n= 47, 45)	45.3 ± 9.5	
Month 6 (n= 45, 43)	44.7 ± 11.5	
Change from Baseline - Month 6 (n= 45, 43)	-0.4 ± 6.9	

No statistical analysis provided for Renal Function Assessed by Change in Estimated Glomerular Filtration Rate(eGFR)

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Trials with GFR Outcomes

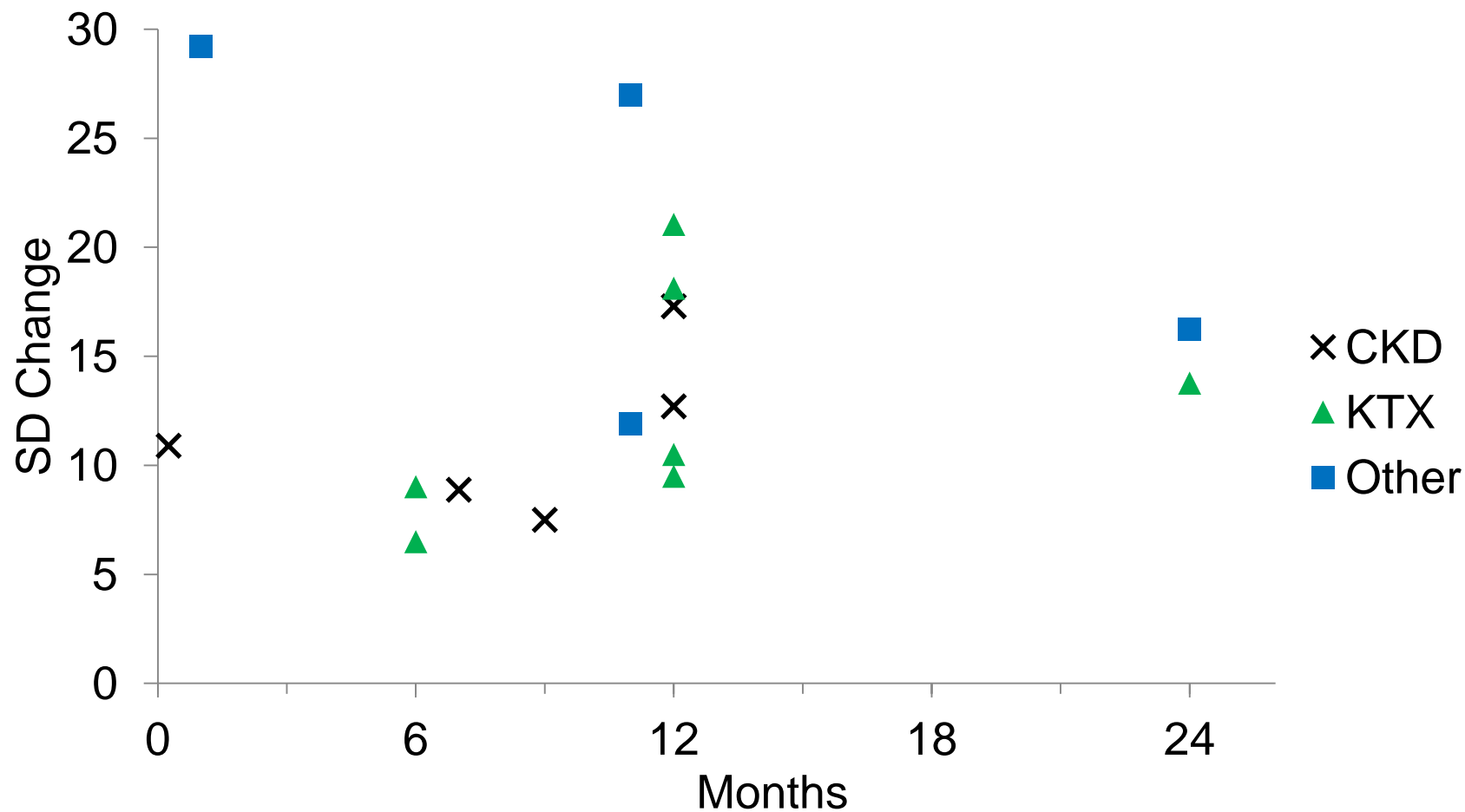


Search performed 11/10/2011

90 Trials Completed 2008-2009

- 38 (42%) of 90 trials have results posted on CTG.
- 44% of the 32 trials with a site in the U.S. have results on CTG compared to 41% of the 58 trials with no sites in the U.S.
- 54% of 65 industry sponsored trials have results compared to 12% of trials not sponsored by industry.
- Publications could not be found for 48 trials, 24 of these had results on CTG.

SD by Trial Duration



CTG Results versus Publication

CTG Results

- Easy to locate trials
- Specified SD or SE
- Data on more secondary outcomes
- Errors can be fixed
- No interpretation by authors

Publications

- Hard to find by NCT #
- More detailed methods
- More complete baseline data
- Easier to read
- Interpretation by authors

Conclusion

- 38 of 90 trials have CTG results including 24 unpublished trials.
- Only 22 of 61 trials with results had change in GFR as an outcome.
- CTG results and publications almost always agreed.
- CTG results database will be more useful as results are submitted for more trials.