MINUTES

CPIC CONFERENCE CALL

DATE: November 3, 2011

PRESENT: Adriana Malheiro, Andrea Gaedigk, Caroline Thorn, Deanna Kroetz, Issam Zineh, Kristine Crews, Mary Relling, Michelle Carrillo, Nita Limdi, Min Song, Rochelle Long, Russell Wilke, Stuart Scott, Teri Klein, Todd Skaar

| TOPIC | DISCUSSION/ACTION | FOLLOW-UP |
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| FDA drug labels (Zineh) | * 1. Reviewed the process for updating drug labels to include pgen information   i. Ways the need for a label change RE pgen to be identified   * + - 1. Internal scan by FDA of literature, etc       2. Researchers, clinicians, patients can petition FDA to make label changes (this is how some early pgen label changes got started)   ii. To actually make the change  1. Need consensus within the FDA (across many offices and areas within FDA); takes time and effort  2. FDA cannot update label themselves – must contact the innovator company; company must agree with FDA or propose different language; 30 day timeframe typical for this part of the process  iii. Location of pgen information in the label  a. New section of label focused on pharmacogenomics; gives additional flexibility  b. Exactly where the information goes in the label depends on the specific situation (e.g. boxed warning, contraindications, dosing, indications, monitoring). Different sections of the label can be cross-referenced   * + 1. Tracking FDA label changes for pharmacogenomics        1. Available on FDA website: <http://www.fda.gov/drugs/scienceresearch/researchareas/pharmacogenetics/ucm083378.htm>        2. A link to FDA website is available on the PharmGKB website <http://www.pharmgkb.org/search/labelList.action> | Continued discussion between CPIC and FDA as needed. |
| Review of guidelines in progress/planned: | * 1. HLA/allopurinol (Lee)      1. Had second conference call      2. Working on involving more rheumatologists – decide best to do when a first draft is available      3. Issam Zineh has a paper on topic in press         1. Data from FDA Adverse event reporting system used in paper         2. Most of data from adults for gout; Most children with leukemia receive it but, it is short term therapy         3. New data -- see Table 2 relationship between HLA-B\*5801 association         4. Some potential for increased use of this drug in metabolic syndrome, which would increase the relevance of the CPIC guideline   2. HLA/carbamazepine (Leckband)      1. Draft has been circulated; now working on supplement      2. PharmGKB staff involved; phone call scheduled   3. SLC01B1/simvastatin (Wilke)      1. Example of gene/drug pair not yet in the label, but there has been FDA action to discourage high dose statin use (avoid 80 mg simvastatin due to risk of myopathy) <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm258338.htm>      2. Homozygotes taking simvastatin had a 20 fold increase risk of myopathy; stronger association at higher doses but association present across all doses      3. Guideline         1. Will be focused on dose dependence with simvastatin myopathy         2. Will discuss if this is a class effect      4. This drug gene/pair is already in use at Vanderbilt      5. Writing team has been established   4. Others: DPYD/5FU, 2D6/2C19/TCAs, 2D6 SSRIs (Mary, Teri)      1. Howard McCleod leading DPYD/5FU      2. 2D6/2C19/TCAs – Jesse Swen/Kevin Hicks      3. 2D6D SSRIs – Caryn Lerman, Susan Leckband, David Mrazek      4. Il-28B Interferon –Andrew Muir at Duke is leader (call scheduled for Nov 23rd   5. Other guidelines      1. CYP2D6/codeine – article in press; just waiting for proofs      2. HLA/abacavir – minor comments received from CPT | Zineh paper was shared with Lee et al.  HLA/CBZ call scheduled for Nov 7th  SLCO1B1/simvastatin to be added to gene/drug pair list on PharmGKB.  Dr. Wilke writing first draft of guidelines.  Names of several volunteers for SSRI and for IL28B guidelines will be forwarded to Lerman/Leckband and Muir respectively. |