**MINUTES**

**CPIC CONFERENCE CALL**

DATE: September 5, 2019

| TOPIC | DISCUSSION/ACTION | FOLLOW-UP |
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| Housekeeping Announcements | Attendance will be taken by poll after each conference call. Members will receive an email with a doodle link after each call. Please enter your first and last name and check the box indicating you were in attendance. No action required if you were unable to make the conference call. | Kelly will send the poll link. |
| Guidelines in progress (not discussed on call) | Guideline updates in progress:* *CYP2C9/HLA/*phenytoin: Drafting recommendation
* *CYP2D6*/opioid: Drafting recommendation; evidence review underway for OPRM1 and COMT
* *CYP2C19/*clopidogrel: Evidence review underway

New guidelines in progress: * *CYP2C19/*PPIs: Drafting recommendation
* *CYP2C9/*NSAIDs: See below
* *mtRNR1*/aminoglycosides: authorship plan underway
 | Guideline preparation will continue and Kelly will continue to follow-up.  |
| *CYP2C9* allele function and new allele function assignment SOP | Kelly reviewed the new allele function assignment SOP. See draft SOP attached with minutes and slides. The authors of the CYP2C9 guidelines and additional CYP2C9 experts recently used the new SOP and the new format for the allele functionality table to evaluate function for CYP2C9 alleles. See slides for discussion points and updates made to the genotype to phenotype table.  | Kelly will continue to update. If you are interested in providing feedback for the allele function assignment SOP, please email Kelly (Kelly.caudle@stjude.org). |
| CYP2C9/NSAID guideline | Katie Theken presented the recommendation tables for the CYP2C9/NSAID guideline. The authors are finalizing the guideline text now and the guideline and supplemental tables will be circulated for CPIC review later this month. | Kelly will continue to update. |
| AMP/CAP recommendations for clinical *CYP2C9* genotyping allele selection | Vicky Pratt presented the AMP/CAP joint recommendations for clinical *CYP2C9* genotyping allele selection (PMID: 31075510; slides attached). | n/a |
| Update on CPIC conversation with FDA | As many of you are aware, several CPIC members have expressed concerns regarding recent FDA comments and requirements for clinical pharmacogenetic testing. We devoted time to this on the August 2019 CPIC call, and have had some conversations with FDA members as well with interested members in the pharmacogenomics field. We have discussed helping to convene a meeting of interested parties. CPIC’s goal is to provide evidence-based guidance on how pharmacogenetic test results be used to guide prescribing, and CPIC staff have quite a full plate in doing the work of reviewing evidence and writing/curating/updating gene/drug pair guidelines. Someone other than CPIC staff would need to take the lead in planning and programming a meeting of interested parties. It is not clear whether FDA staff would attend such a meeting.Two groups, the American Society of Pharmacovigilance (ASP; <http://www.stopadr.org/>) and the Precision Medicine Coalition (PMC), have ongoing initiatives to address this issue. PMC’s Public Policy Committee is scheduled to discuss the future regulation of pharmacogenomics. Details to come.  One option that has been suggested by members of the FDA staff would be to form a Collaborative Community on this issue, as described: https://www.fda.gov/about-fda/cdrh-strategic-priorities-and-updates/collaborative-communities-addressing-healthcare-challenges-together. Another option the FDA recommended was for CPIC to become a “recognized” genomic database. CPIC and PharmGKB are looking into possibilities for such recognition.  | Mary and Teri will continue to update CPIC members. |