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## 2016–2017 Activities and Accomplishments

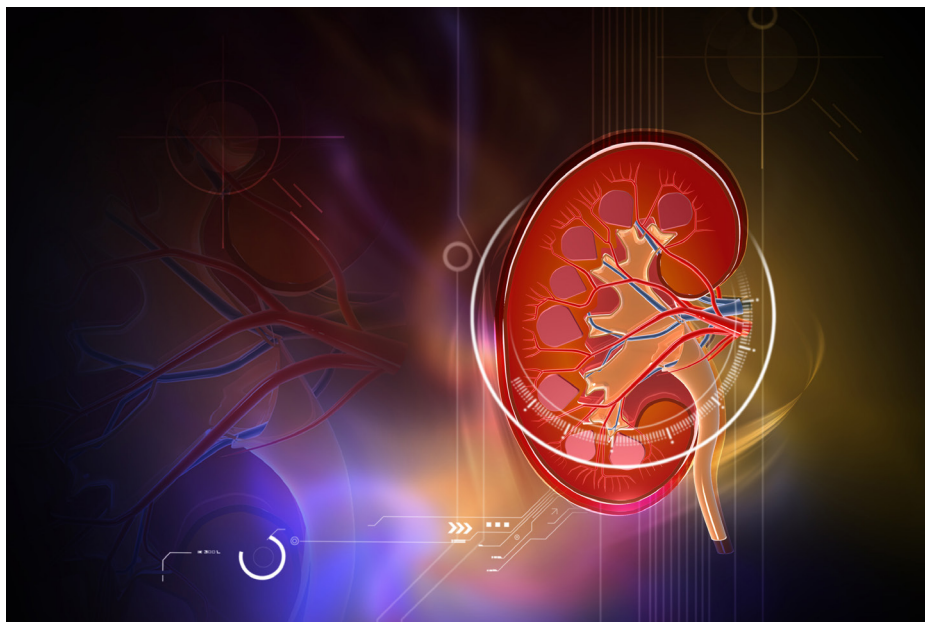
### Committee leaders:

Dr. Ernie Harpur  
Newcastle University

Dr. Jean-Charles Gautier  
Sanofi

### HESI manager:

Dr. Raegan B. O’Lone



### This scientific program is committed to:

- Advancing the scientific basis for the development and application of biomarkers of nephrotoxicity with an emphasis on the identification of markers that bridge from animal to human models.

### Areas of scientific focus:

- Exploring microRNAs as markers of renal injury.
- Defining best practices in the experimental practice of urinary biomarker collection and analysis.

### Why get involved?

- Gain novel insights into the utility of renal-associated microRNAs for safety evaluation and decision making.
- Collaborate on identifying best practices in urinary and serum biomarker collection to increase the quality and consistency of study data, and thus support more effective use of these data for decision making.

### Key accomplishments:

- *Evaluation of MicroRNAs as Renal Biomarkers.* A multi-laboratory program with toxicants specific for particular nephron segments has been conducted to explore urinary microRNA expression in rodents toward discovery of novel microRNA markers of site-specific nephrotoxicity. Findings from several of the individual studies have been published, and meta-analysis across studies has been conducted toward identifying promising biomarker candidates. The committee is initiating follow-up studies to further identify the region specificity and expression of promising microRNA biomarker candidates. The committee has also been further exploring potential site-specific microRNAs in large animals in collaboration with the Predictive Safety Testing Consortium. Manuscripts describing the outcome of this work will be published.
- *Assessment of Current Practices in the Technical Evaluation of Urinary Biomarkers.* The committee collected information via a survey and summarized the results on urine collection and biomarker assessment practices. The survey findings stimulated discussion on knowledge gaps and led to design and conduct of follow-up experiments to further evaluate effects of collection and assessment methods and sample storage duration on biomarker measurements. A manuscript summarizing the outcome of this project is in preparation.

### The Committee’s focus for May 2017–May 2018:

- Analyze pooled input from committee members and data generated to assess best practices in urinary and serum biomarker collection methods.
- Prepare a manuscript describing the outcome of the multi-study meta-analysis assessing microRNAs in urine associated with exposure to renal toxicants.
- Conduct confirmatory experiments to further characterize localization and expression of select microRNAs identified in the multi-laboratory study.

**2016–2017 Participating organizations**

Astellas Pharma Inc.  
Biogen Inc.  
Bristol-Myers Squibb  
Harvard University  
Janssen Pharmaceuticals  
Liverpool John Moores University  
Newcastle University  
National Institute of Environmental Health Sciences  
Pfizer  
Sanofi  
University of North Carolina

For more information, contact the Committee's manager, Dr. Raegan B. O'Lone, [rolone@hesiglobal.org](mailto:rolone@hesiglobal.org).