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## Key Dates

<b>Opening Date</b> .....	April 2, 2018
<b>Letter of Intent Due</b> .....	May 24, 2018
<b>Notification to Proceed with Full Paper</b> .....	June 15, 2018
<b>Full Paper Submission Deadline</b> .....	August 15, 2018
<b>Anticipated Award Notification</b> .....	September 15, 2018
<b>Event to Showcase Award Winners</b> .....	November/December 2018 (Location TBD)

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## Challenge Award

Personalized medicine – in which prevention and treatment strategies are guided by genetic tests, other biomarkers, and patient preference – is taking hold as a significant element of clinical care, particularly in the field of oncology. In 2017, FDA approved a record number of targeted medicines. The field of precision medicine has given rise to, and been enabled by, increasingly sophisticated electronic health data systems capable of capturing and analyzing large volumes of genetic, clinical, and patient-generated data. Thought leaders are seeking to harness this capacity to rethink health care and drive unprecedented transparency around the value of health care. Yet, conventional methods for value assessment remain rooted in conventional, population-level methods and evidence hierarchies.

The Foundation and Personalized Medicine Coalition are seeking papers that describe solutions to the following question: What are potentially transformative strategies and methods to define and measure value at all levels of decision making that are aligned with personalized/precision medicine?

Examples may include, but are not limited to:

- Develop tools to facilitate value-based personalized decision-making based on an individual patient’s specific genetic characteristics and preferences
- Propose a mechanism to incorporate individual patient characteristics into value assessment so as to appropriately value treatments at the patient level.
- Define a set of measures to capture health care value that can be integrated into a framework to support decision-making from different perspectives
- Generate instruments capable of capturing relevant and standardized measures of value
- Design value-based or outcomes-based contracts that incentivize improved quality, sustainability and continued innovation in medical devices, diagnostics and medicines
- Build decision-making tools that adapt behavioral economic principles to promote value

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## Award Funding Details

Recipients of Challenge Awards will be honored and asked to present their winning papers at a public forum in 2018. Awards will be given in the following amounts:

- The winner will receive \$50,000
- The runner up will receive \$25,000
- Third and fourth place will receive \$5,000

Evaluations of specific healthcare interventions will not be supported.

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## Application Process

The Challenge Award application process has two stages.

- 1 Candidates should submit letters of intent (LOIs) to Eileen Cannon, President, PhRMA Foundation, at [Foundation@PhRMA.org](mailto:Foundation@PhRMA.org) no later than May 24, 2018, to initiate the application process. LOIs will be reviewed for potential program fit, novelty, importance, rigor and clarity.
- 2 Qualified applicants will be contacted no later than June 15, 2018, with a request to submit the full paper describing their response to the challenge question. Papers are due August 15, 2018, and will be evaluated by a panel of qualified reviewers.

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## Award Expectations

The PhRMA Foundation is committed to driving real change in health care delivery and recognizes the benefit of shared knowledge. Therefore, the Foundation will establish a Value Assessment Research Network to encourage collaboration and dissemination of findings borne out of the program.

Recipients of all PhRMA Foundation awards under the Value Assessment Initiative will become members of the Network and be asked to participate in periodic calls or in-person meetings to discuss and drive advancement in the field.

The PhRMA Foundation will host a public forum in 2018 to highlight activities funded by this program. Awardees must be willing and available to present their winning papers at this forum.

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## Eligibility

Award opportunities are open to all individuals and organizations with training in health economics, outcomes research, clinical sciences or health care evaluation. Eligible applicants should hold an advanced degree in a field of study logically or functionally related to the proposed activities. Collaboration across stakeholder groups and fields of discipline is encouraged.

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## Letter of Intent and Application Considerations

Evaluating the value of health care interventions is challenging. But, when designed well and used appropriately, tools that quantify the value of a health care treatment can inform decision-making for patients, providers and payers. There are several criteria to consider in developing solutions to drive high-quality value assessment.

**Stakeholder Engagement** A vital step to a successful shift toward a value-driven health care system is ongoing engagement with stakeholders. It is particularly important to incorporate patient perspectives and acknowledging that all individuals are future recipients of health care and are driving factors of high-quality value assessment. Recommendations for patient engagement processes are made available by the National Health Council.<sup>i</sup>

**Real-World Applicability** All funded activities should generate resources, evidence or ideas that can be applied feasibly in the U.S. health care system. Variations in practice patterns or disparities in care (e.g., demographics, socioeconomic status and type of insurance) should also be acknowledged.

**Adherence to Best Practices** Proposed methodology should follow relevant, well-accepted recommendations, such as those published by the Agency for Health Care Research and Quality, International Society for Pharmacoeconomics and Outcomes Research, National Pharmaceutical Council Guiding Practices for Patient-Centered Value Assessment or Second Panel on Cost-Effectiveness in Health and Medicine.<sup>ii</sup>

**Review and Validation** Research activities should be subject to systematic ongoing validation to ensure that accurate, truthful and non-misleading and reproducible findings are generated. Results should not be disseminated until validated through expert review, with input provided by all relevant and qualified stakeholders. The process of review should be well-documented and accompany the dissemination of the results.

**Patient-Centered Decision-Making** Value assessment tools create opportunities to support patient-centered decision-making, if patients and other stakeholders are able to review and customize value information based on their own preferences. For example, the second panel on cost effectiveness in health and medicine recommends that all potential consequences of care should be presented in a transparent and disaggregated form, such as in an “impact inventory table”.<sup>iii</sup> Additionally, all criteria should be quantified and included in assessments, if possible.

**Addressing Uncertainty** Tools or frameworks that assess care value should adequately explain and address all sources of uncertainty (e.g., in parameter selection, decision process, measurement) and conduct and present relevant sensitivity and scenario analyses.

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## Submission Components

This program is requesting that prospective candidates submit a letter of intent prior to the submission of a paper. The letter of intent should include the following:

Letter of Intent Components:

- 1 Descriptive title of proposed paper
- 2 Name, address and telephone number of the applicant(s)
- 3 Names of other key personnel (if applicable)
- 4 Applicant(s) CV or biosketch
- 5 Affiliated or participating institutions (if applicable)
- 6 Proposed response to challenge question, not to exceed 600 words

Paper Submission Components::

- 1 Descriptive title of proposed paper
- 2 Name, address and telephone number of the applicant(s)
- 3 Names of other key personnel (if applicable)
- 4 Applicant(s) CV or biosketch
- 5 Affiliated or participating institutions (if applicable)
- 6 Response to challenge question in a paper suitable for publication, not to exceed 3,000 words

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## References

- i National Health Council, Patient Engagement. Available at: <http://www.nationalhealthcouncil.org/public-policy/patient-engagement>
- ii Agency for Health care Research and Quality (AHRQ) Guidance for the Conduct and Reporting of Modeling and Simulation Studies in the Context of Health Technology Assessment. Available at: <http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?productid=2315&pageaction=displayproduct>;  
International Society for Pharmacoeconomics and Outcomes Research Good Practices for Outcomes Research Practices. Available at: [https://www.ispor.org/workpaper/practices\\_index.asp](https://www.ispor.org/workpaper/practices_index.asp);  
National Pharmaceutical Council Guiding Practices for Patient-Centered Value Assessment. Available at: <http://www.npcnow.org/guidingpractices>;  
Sanders GD, Neumann PJ, Basu A, et al. Recommendations for Conduct, Methodological Practices, and Reporting of Cost-effectiveness Analyses: Second Panel on Cost-Effectiveness in Health and Medicine. *JAMA*. 2016;316(10):1093-1103. doi:10.1001/jama.2016.12195.
- iii Sanders GD, Neumann PJ, Basu A, et al. Recommendations for Conduct, Methodological Practices, and Reporting of Cost-effectiveness Analyses: Second Panel on Cost-Effectiveness in Health and Medicine. *JAMA*. 2016;316(10):1093-1103. doi:10.1001/jama.2016.12195.