

## 3 Step Prize Review: Antimicrobial Resistance Diagnostics Challenge

Gagan Pandya; SRO IDM Alexander Politis; IDM Chief

## The Antimicrobial Resistance Diagnostic Challenge

- Federal prize competition not a grant or a contract
- Challenge competition allows federal agencies to crowdsource ideas from public to address issues that affect people, communities, and industries
- Since 2010, the U.S. government has run nearly 1,000 challenges and offered ≥ \$250 million in cash prizes for the best ideas.
- AMR Diagnostic Challenge prize is \$20 million the largest prize announced so far





Department of Health and Human Services

### Visualization Resources of Community-Level...

Challenge.gov

Can you develop a visualization tool to enhance the research and analysis of community-level health services?

#### \$220,000 IN PRIZES

Open Until: 06/07/2019



on Drug Abuse

Department of Health and Human Services

### 2018 "\$100,000 for Start a SUD Startup" Challenge

Test the premise of research ideas that can be fostered into biotech startups

#### VIEW THIS CHALLENGE

Closed On: 01/15/2019



Department of Health and Human Services

### Remote Pregnancy Monitoring Challenge

Propose tech ideas to help connect pregnant women with prenatal care



Department of Health and Human Services

### DEBUT (Design by Biomedical Undergraduate...

NIBIB is challenging undergraduate students to develop engineering solutions to unmet clinical needs!

#### \$45,000 IN PRIZES

Open Until: 05/31/2019



Department of Health and Human Services

### KidneyX: Redesign Dialysis Phase 1

Redesign the future of kidney care

#### \$2,625,000 IN PRIZES

Closed On: 02/28/2019





Department of Health and Human Services

### Addressing Opioid Use Disorder in Pregnant...

Find solutions to help pregnant women & new moms with opioid use disorder.





Department of Health and Human Services

### Shape of Health: An Obesity **Prevention Game**

Create an interactive video game with focus on obesity prevention or weight control for women or girls.

#### \$200,000 IN PRIZES

Open Until: 03/31/2019



Department of Health and Human Services

### NCATS Rare Diseases Are Not Rare! Challenge

Share innovative ways to communicate to educate people about rare diseases through social media or art

### \$5,000 IN PRIZES

Closed On: 10/31/2018





Department of Health and Human Services

### NEI 3-D Retina Organoid Challenge 2020: Reduction...

Build your vision of the future

# Goal and Structure of the Challenge

Goal: innovative, rapid, POC diagnostic test(s) to combat the development and spread of drug resistant bacteria. - Joint effort between NIH (NIAID) and BARDA – launched as a 3-step competition

Step 1	Conceptual	Sept 8, 2016 – March 27, 2017
Step 2	Prototype Analytical Data	March 28, 2017-Dec 3, 2018
Step 3	Performance Testing in CLIA Labs	Dec 4, 2018-July 31, 2020

- Step 1: \$50K /semi-finalist max 20 awards (10 awardees)
- Step 2: \$100K /semi-finalist max 10 awards (5 awardees)
- Step 3: \$18.5M for maximum of 3 awardees



## **Review: Unusual Attributes**

- Letter Of Intent is Required
- Submissions not through grants. gov
- Compressed timeline:
  - 3-4 weeks to finalize roster & make review assignments
    - □ Pre-recruitment of panel expertise
  - 4 weeks for reviewers to generate critiques
  - 2 weeks: generate summary statements & reports
    - □ Team of several SROs
- Emphasis on review criteria all reviewers provide criterion scores
- Solver does not receive scores or summary statement



# **Guide to Step 2 AMR Challenge Criterion Scores\***

Criteria	1 2 3 STRONG	4 5 6 MODERATE	7 8 9 WEAK	
Innovation	Technical Innovation	Using Established Technologies in New Ways	Minimal/No Evidence of New Technology or Concepts	
Clinical Significance	Distinction of Viral vs. Bacterial and/or Addressing Multiple AMR Pathogens = High Impact, Highly Impactful in Antibiotic Stewardship	Higher Threat Level <sup>†</sup> =Better Score, Moderately Impactful in Antibiotic Stewardship	Unlikely to Address Any Challenge Goals, Minimally Impactful in Antibiotic Stewardship	
Diagnostic Performance and Feasibility	Sensitivity-LOD/Specificity Superior to Existing Methods, Claims Based on Sound Principles Supported by Convincing Data, Mature Prototype	Performance Displays Moderate Advancement Over Existing Methods, Some Concerns Related to Claims, Prototype in Late Stages of Development	Little/No Advancement Over Existing Methods, Doubts Related to the Claims Made, Prototype in Early Stages of Development	
Sample Matrix/Setting and Ease of Use/Throughput	Easy to Collect and Process Samples, Minimally Invasive, Simple Method to Perform, Easily Fits in Existing Clinical Workflow, High Throughput	Samples Somewhat Invasive,  Moderate Processing,  Moderate Training to Cope  with Technology, Need to  Modify Existing Clinical  Workflow, Moderate  Throughput	Sample Collection and Processing Concerns, Difficult to Implement Technologically Complex Method, Unable to Assess Simultaneous Samples	
Arrows within the Moderate category indicate that these are considerations that could lead to a stronger or a weaker view				
* Goal is to discriminate merit with reviewers using a consistent approach to scoring				
† CDC's Antibiotic-Resistant Threats in the United States				



## **CSR Contributions**

- Open eligibility to submit a Step 2 solution (Not limited to Step 1 Winners)
- COI concern: reviewers not eligible to submit solutions
- Independent assessment of each criterion
- Step 2
  - Replace prototype submission with photos & video
  - 8 Criteria → Reduced to 4 with revision of solution format
  - Designed Letter of Intent to prepare for conflicts and needed expertise

☐ Step 1: Suggested (not approved) to provide solvers with summary statement



## **Step 3: Performance Testing in CLIA Certified Laboratories**

- Prototype submission deadline: January 3, 2020
  - Up to 5 submissions at Step 3
- CLIA-certified independent lab testing: by April 2020
- Technical Evaluation Panel Meeting: May/June 2020
- Awardee(s) announcement: July 31, 2020



# **Acknowledgement: Team work**

### SRO - IDM

- Guangyong Ji
- John Pugh
- Kenneth Izumi
- Liangbiao Zheng
- Marci Scidmore
- Neerja Kaushik-Basu
- Soheyla Saadi
- Susan Daum
- Tamara McNealy

### SRO - IMM

- David Winter
- Liying Guo

### SRO - EMNR

- Clara Cheng
- Dianne Hardy

## SRO - AARR

- Joanna Pyper (contractor)
- Robert Freund

## ESA (IDM)

- Lauren Brand
- Nisrin Suterwala
- Seo Young Hong

## eRA/DRR

- Aaron Czaplicki
- Cathleen Cooper
- Laurie Roman

## **BARDA**

- Rodney Wallace
- Rosemary Humes

### **IMB**

- Leo Wu
- Lin Yang
- Maya Jones
- Rashid Shah
- Rong Bi

### CCC

- Barbara Singer
- Jennifer Adona
- Susan Kerin

## **NIAID**

Robert Eisinger

