

National Institute of Allergy and Infectious Diseases

Preclinical efforts to support gonorrhea drug development

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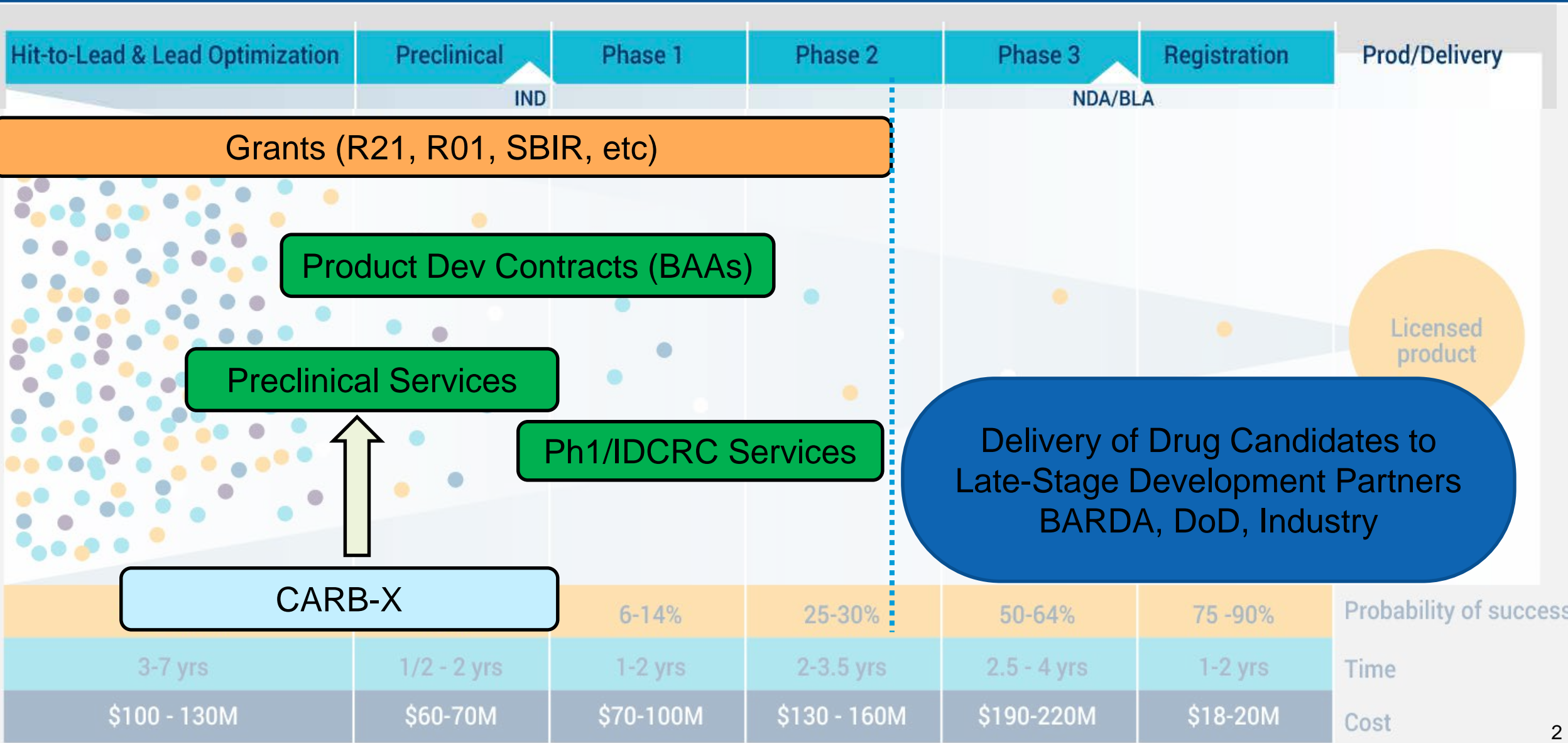
Development Considerations of Antimicrobial Drugs for the Treatment of Gonorrhea



National Institute of
Allergy and
Infectious Diseases

NIAD

DMID Support Reduces Risk for Product Development



Pre-Clinical Services Supports Product Development by Extramural Investigators



DMID supports extramural research to control and prevent diseases caused by virtually all human infectious agents, except HIV

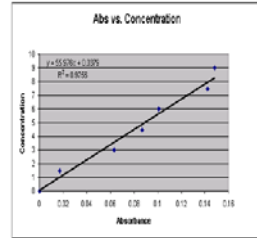
- DMID preclinical services programs:
 - Provide broad-based services supporting preclinical product development
 - Provide project or product-specific data
 - Provide difficult-to-source research reagents
 - Facilitate basic research through all phases of preclinical development
 - **Are intended to be gap-filling**
 - **Have no requirement for existing NIAID or NIH funding**

Preclinical Services:

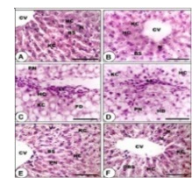
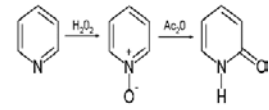
Provides critical data to evaluate candidate MCMs

Therapeutics

In Vitro Assessment of Antimicrobial Activity



Interventional Agent



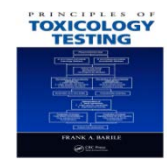
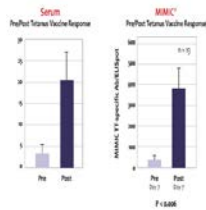
Biopharmaceutical Products



Chemistry, Manufacturing, and Controls (CMC) Documentation for IND

Vaccines

Testing



Manufacturing



External Requests: full suite of capabilities to address key gaps

Outbreak Response: Rapid access to evaluate interventions

Research Resources



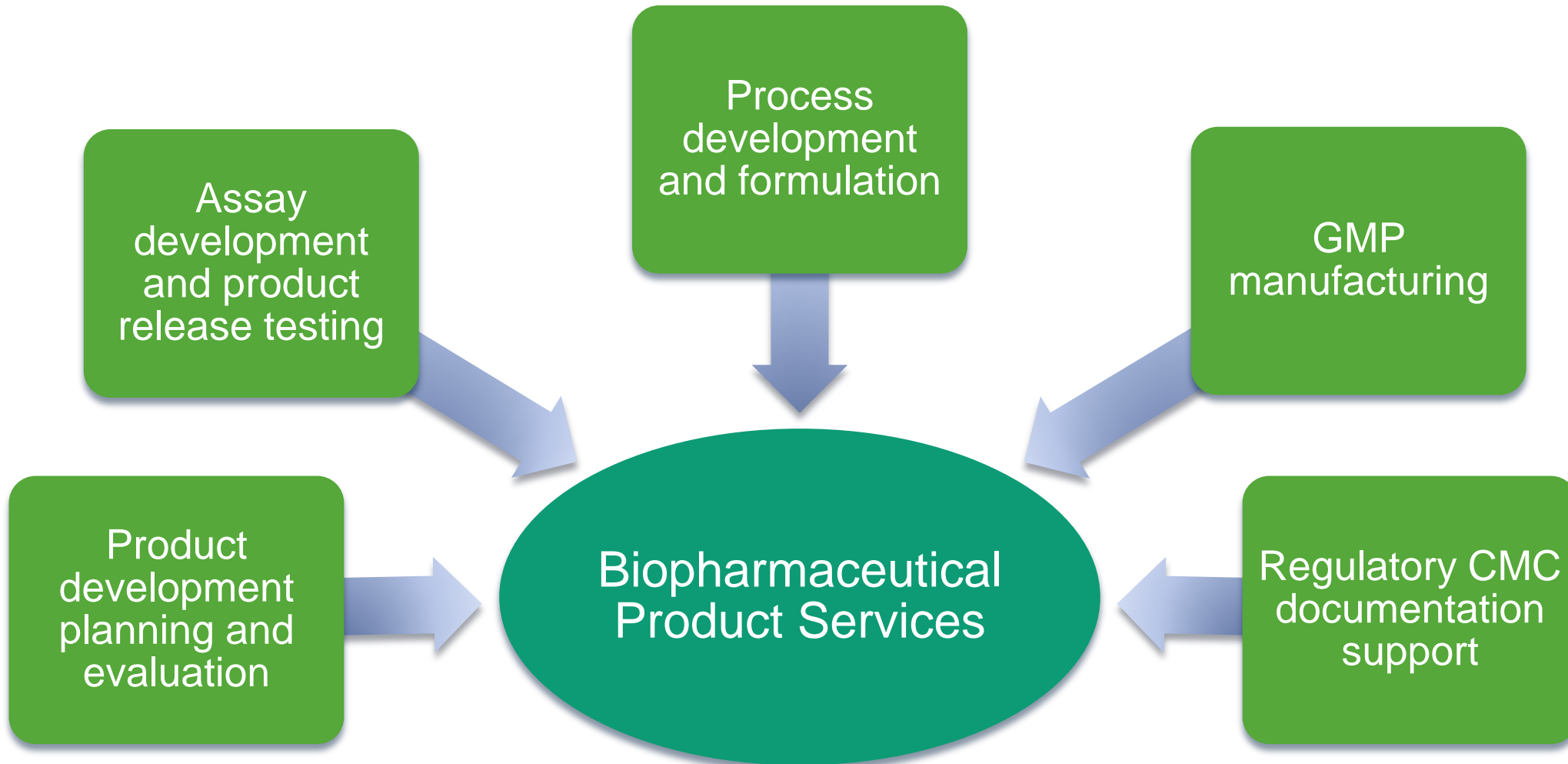
bei RESOURCES

SUPPORTING INFECTIOUS DISEASE RESEARCH

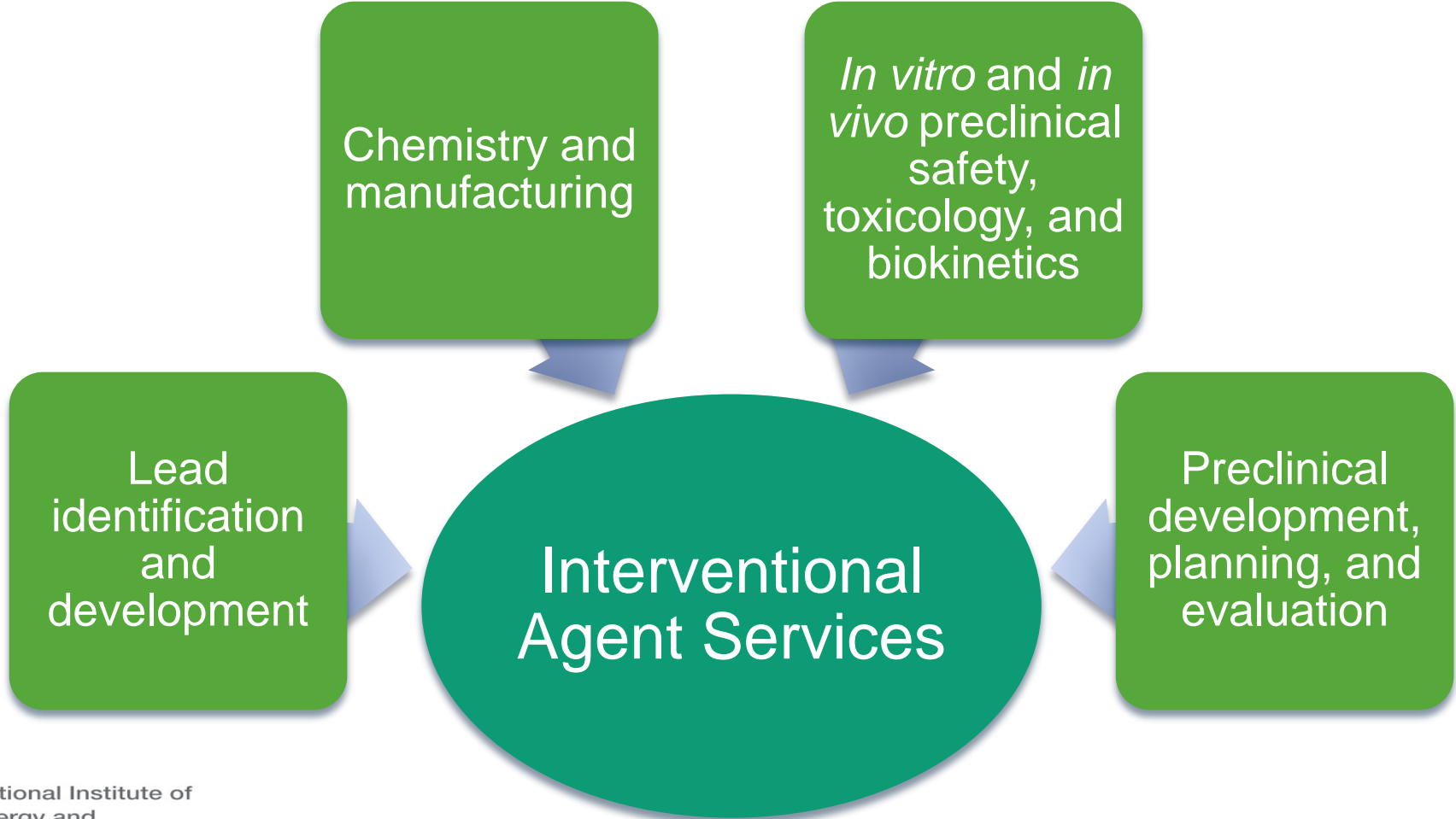


NIAID

Types of Services: Therapeutics Development



Types of Services: Therapeutics Development



Neisseria gonorrhoeae MIC Testing Task Order

- *In vitro* Assessment of Antimicrobial Activity
 - 100 clinical isolates from the CDC Gonorrhea Isolate Surveillance Project (GISP)
 - Recent
 - Geographical diversity (U.S. only)
 - Diverse Abx sensitivities (≤ 0.125 ug/ml ceftriaxone)
 - CLSI agar dilution method
 - 6 control antibiotics (Pen, Tet, Azi, Cip, Ceft, Cefx)
 - 2 months from receipt of compound(s)

Mouse gonorrhoea infection model Task Order

- Preclinical models of infectious diseases
- Ovariectomized, 17 β -estradiol treated BALB/c mouse model
- FA1090 Challenge strain
- Typical experiment:
 - Up to 10 groups of 5 mice per group
 - Baseline group sacrificed at 2hrs to determine dose
 - Ceftriaxone positive control group
 - Vehicle/negative control group
 - Test groups
 - Colony counts at 26hrs post challenge

Contacts

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- Interventional Agents, pcs.ia@mail.nih.gov
- Biopharmaceutical Products, pcs.bp@mail.nih.gov
- **Wesites:**
 - **Preclinical Services:**
<https://www.niaid.nih.gov/research/resources?f%5B0%5D=division%3A12&f%5B1%5D=stage%3A264>

New diagnostics for gonorrhea

- Klausner JD, Bristow CC, Soge, OO and et al, Resistance-Guided Treatment of Gonorrhea: A Prospective Clinical Study. Clinical Infectious Diseases. Clin Infect Dis. 2020 Aug 7:ciaa596. doi: 10.1093/cid/ciaa596. <https://pubmed.ncbi.nlm.nih.gov/32766725/>

Wednesday, August 5, 2020

Rapid diagnostic for gonorrhea wins \$19 million federal prize competition to combat antibiotic resistance

