

Call for Proposals – Innovative *S. aureus* and *E. coli* preventatives

It is well established that antibiotic-resistance is prevalent among clinically relevant resistant *S. aureus* strains and attempts to develop vaccines against invasive disease caused by this pathogen have showed a lack of safety, efficacy, or both. Similarly, scientific barriers have prevented the successful development of a vaccine for *E. coli*, whether of enteric or urinary etiology. Therefore, this funding call allows for truly innovative approaches, other than vaccines or mAb described elsewhere.

Minimal Entry Criteria for this innovative preventative-focused funding solicitation are as follows:

- a. Proof of concept data:
 - i. Demonstration of the postulated mechanism of protection *in vitro*, including an assessment of potential resistance mechanisms.
 - ii. Plan to obtain proof-of-concept data, i.e., a demonstration of protection against a clinically relevant manifestation of *S. aureus* or *E. coli* infection in a preclinical animal model.
 - iii. Implemented test cascade that will allow for rapid iteration to optimize the agent, plus an assessment as to how many iterations will be needed.
- b. Proposed workplan should include
 - i. TPP, listing key performance characteristics and appropriate disease indication, similar to those of vaccines and mAb
 - ii. Activities to assess and improve the current characteristics to that of a clinical lead.
 - iii. High-level vision for how this novel approach would be clinically and commercially developed, and in which target population(s), as well as a high-level regulatory strategy.