The Sequence of Success: Antibiotic Alternative Development from the Startup Perspective

2\textsuperscript{nd} International Symposium on Alternatives to Antibiotics
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EpiBiome is a precision microbiome engineering company.
Our mission is to surveil microbial populations and to develop the technologies that will protect humanity against the rising global threat of antibiotic resistance.
Why Develop an Antibiotic Alternative For Dairy Cattle?

- Concerns about use of antibiotics in food animals
- Proof of concept for other applications
- Unmet clinical need
- One Health approach to infectious disease
The Cycle of Death

Burn Rate

Flame Date
Challenges for a Startup

Money
No revenue; reliant on dilutive and non-dilutive funding

People
One person wears multiple hats; cost of consultants and advisors

Equipment/Materials
Access to capital equipment, bacterial reference libraries, etc.

Space/Facilities
Access to research facilities, lab space, etc.

Animal Studies
Every study represents major investment and major decision point

Technical Risk
Doing basic research alongside development

Market
Value proposition and market adoption

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How Can Regulators Help – “Inside the Box”

- Early Information meetings
  - Clarifies path to approval
  - De-risks investment for investors
- Barrier to Innovation Waiver
- Flexibility in claims structures
- Slaughter Authorizations
- Harmonization***
How Can Regulators Help – “Outside the Box”

• Develop toolkits for startups
  • NHLBI Small Biz Hangouts
  • Workshops
NHLBI Small Biz Hangouts
NHLBI • 16 videos • 1,682 views • Last updated on Aug 1, 2016

1. NHLBI Small Biz Hangouts: Conquering the (Regulatory) Basics | Navigating the FDA Website
   by NHLBI
   49:36

2. NHLBI Small Biz Hangout: First Contact with FDA
   by NHLBI
   1:03:29

3. NHLBI Small Biz Hangout: Medical Device Regulation Overview
   by NHLBI
   58:00

4. NHLBI Small Biz Hangout: Biologics Regulation Overview
   by NHLBI
   53:54

5. NHLBI Small Biz Hangout: Writing Your Phase II Commercialization Plan
   by NHLBI
   1:02:04

6. NIH Small Biz Hangout: Finding the Right Regulatory Consultant
   by NHLBI
   50:15
How Can Regulators Help – “Outside the Box”

- Develop toolkits for startups
  - NHLBI Small Biz Hangouts
  - Workshops
- Expanded access under INAD
- GAIN Act (GAIN-like)
- Voucher/coupon system
- Reformulation
- Elements of MUMS (Designation)
Time is Money, and Money is Money
A pessimist sees the difficulty in every opportunity; an optimist sees the opportunity in every difficulty.

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