

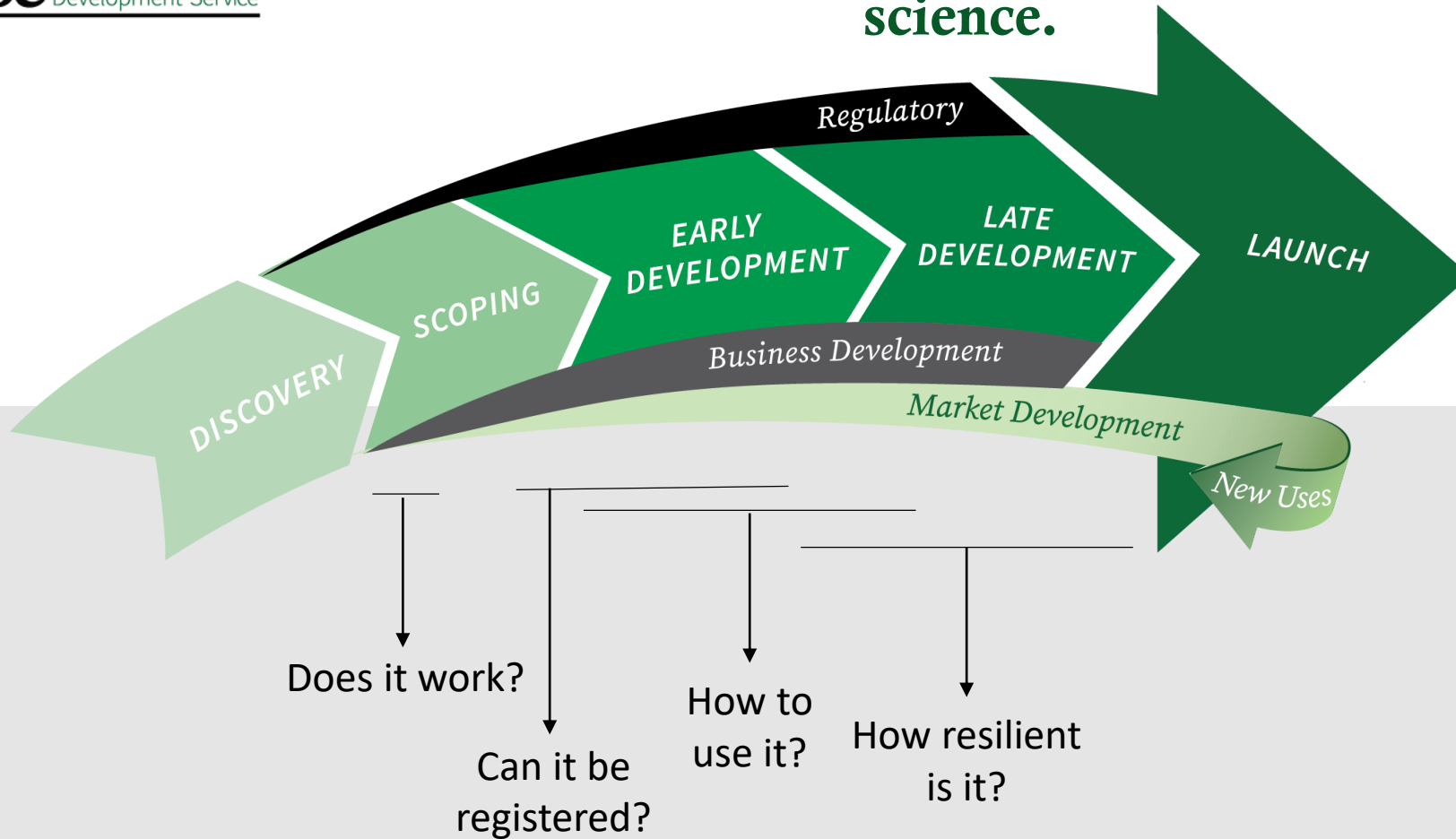
*Challenges for the
development of*

BIOLOGICAL PRODUCTS



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**Product Development is as much
about process as it is about
science.**



Regulatory requirements

Importation required?

- Risk for product availability = Risk for execution
- Careful planning required (time)

Release permit required?

- Careful planning required (time)
- Permit requirements and obligations = potential liabilities

Genetically Modified Microbes?

- Containment x Monitoring
- Detection Method
- Record Keeping
- Caution Genome Editing is NOT always de-regulated
- SPECIAL attention to release permits and obligations = liabilities

Regulatory trials?

- GLP requirements

Can it be registered?



Key challenges for Biologicals:

1

PLANNING

2

UNIQUE REQUIREMENTS

3

GMO Microbes

Scoping

Is your product sample viable?

- Especially important with microbes

“Does it work” trial?

- Proof of concept
- One or very few trials
- It is NOT a real-life trial
- Carefully designed protocol
- Some degree of environmental control
- Subtle effects: replications
- Maximize expression of potential effects
- Avoid multiple objectives

Go/No Go?

- Complex, but intellectually stimulating trials
- Opportunity to engage truly new technologies

Does it work?



Key challenges for Biologicals:

1

FOCUS

2

SUBTLE EFFECTS

3

PRODUCT CONCEPT

Early Development

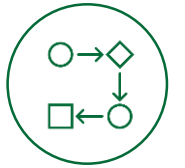
Is your product sample viable?

- Especially important with microbes

“How to use” trials?

- Narrowing variables
Formulation, rates, application
- Few already close to real-life trials
Attention to CV
- You may be part of a small network
Consistency on execution
Avoid protocol changes
Choose meaningful checks
- Investment for the later stages
Increased effectiveness of future trials

How to use it?



Key challenges for Biologicals:

1

DEFINITION OF PERFORMANCE

2

FIT THE PARADIGM

3

POSITIONING

Late Development

Is your product sample viable?

- Especially important with microbes

“Resilience” trials?

- Test the variability of performance
 - Several locations, multiple years*
 - Few variables (e.g. rates)*
- You ARE part of a large network
 - Several real-life trials*
 - Consistency on execution*
 - Avoid protocol changes*
- Stand Alone x Programs

How resilient is it?



Key challenges for Biologicals:

1

CONSISTENCY OF PERFORMANCE

2

MITIGATION MEASURES

3

NEED FOR NEW PARADIGM?

3

STAND ALONE X PART OF A PROGRAM

Thank you!

AGRI^THORITY[®]
Science without Borders

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