

# **Business Development: Identifying R&D Opportunities for Strategic Growth**

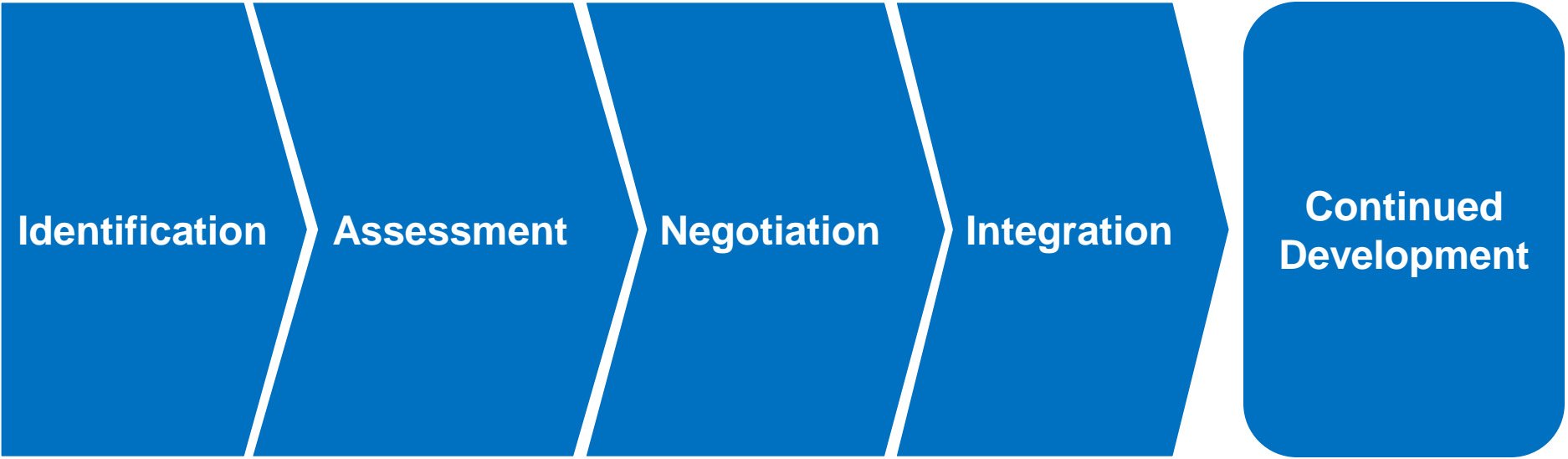
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# What is Strategic Growth?



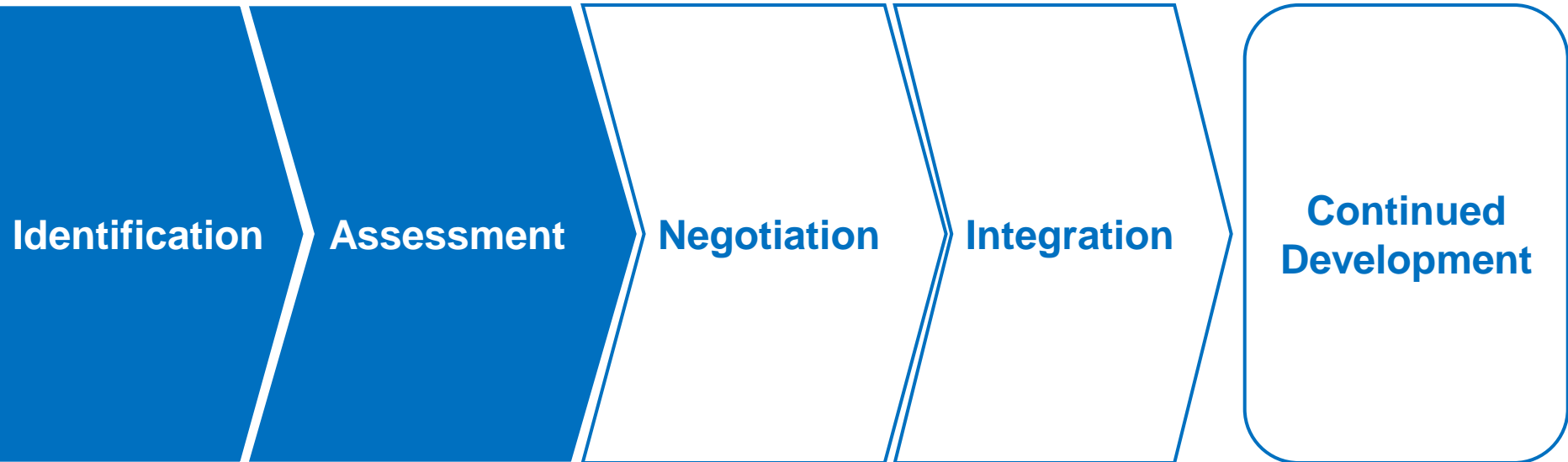
# The Process of Evaluating Opportunities

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# Identifying and Assessing Opportunities

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# Considerations when Identifying and Assessing Opportunities

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- Indication
- Target / Mechanism of Action
- Modality
  - protein/peptide, antibody, small molecule, etc
- Clinical Development Plan
- Manufacturing
- Intellectual Property
- Commercialization



# What is the Indication?

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- ▶ Is there an unmet need?
- ▶ What is the potential patient population?
- ▶ Are there ways to improve upon current treatments?
- ▶ Are there good preclinical models?
- ▶ Is it a fit within the organization?



# Mechanism of Action and Modality

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- ▶ Is it novel?
- ▶ Existing research and studies?
- ▶ Protein / peptide?
- ▶ Antibody?
- ▶ Small molecule?
  
- ▶ These have important efficacy and safety implications
  - ▶ Downstream pathway effects
  - ▶ Toxicology profile and off target effects
  - ▶ Immunogenicity
- ▶ Dosing and administration implications



# Development Plan and Manufacturing

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## ▶ Development Plan

- ▶ Is there a known regulatory path?
- ▶ What effect size is anticipated?
- ▶ What risks are anticipated and can they be mitigated?
- ▶ Is it feasible to design an appropriate study?
- ▶ How long and big will the clinical trials need to be?

## ▶ Manufacturing

- ▶ What is the “cost of goods”?
  - ▶ Formulation issues
  - ▶ Storage and Stability
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# Intellectual Property and Commercialization

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- ▶ Intellectual Property
  - ▶ Does it have protection?
- ▶ Commercialization
  - ▶ Will this be first to market?
  - ▶ Best-in-class?
  - ▶ How long before generics / biosimilars can enter the market?
  - ▶ Is there a current sales force?
  - ▶ Will it be acceptable to payers?



# Identifying and Assessing Opportunities Requires Experience and Collaboration

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- ▶ Chemistry / Protein Sciences
- ▶ Protein Sciences
- ▶ Research
- ▶ Toxicology
- ▶ PKPD
- ▶ Clinical Development
- ▶ Regulatory
- ▶ Safety
- ▶ Manufacturing
- ▶ Legal
- ▶ Commercial



Thank you

