

Canada Organizations as Key Contributors to Canada's S&T Strategy

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BIOMEDICAL TECHNOLOGIES

- Therapeutic products (small molecules, biologics)
- Diagnostic technologies
- Drug/Device Combination
- Functional foods/ Nutraceuticals



Product Development

Cradle  Sky/Grave



Concept
Development

Strategy
Feasibility

Design Product
and Process

Prototype

Tech
Transfer

Support

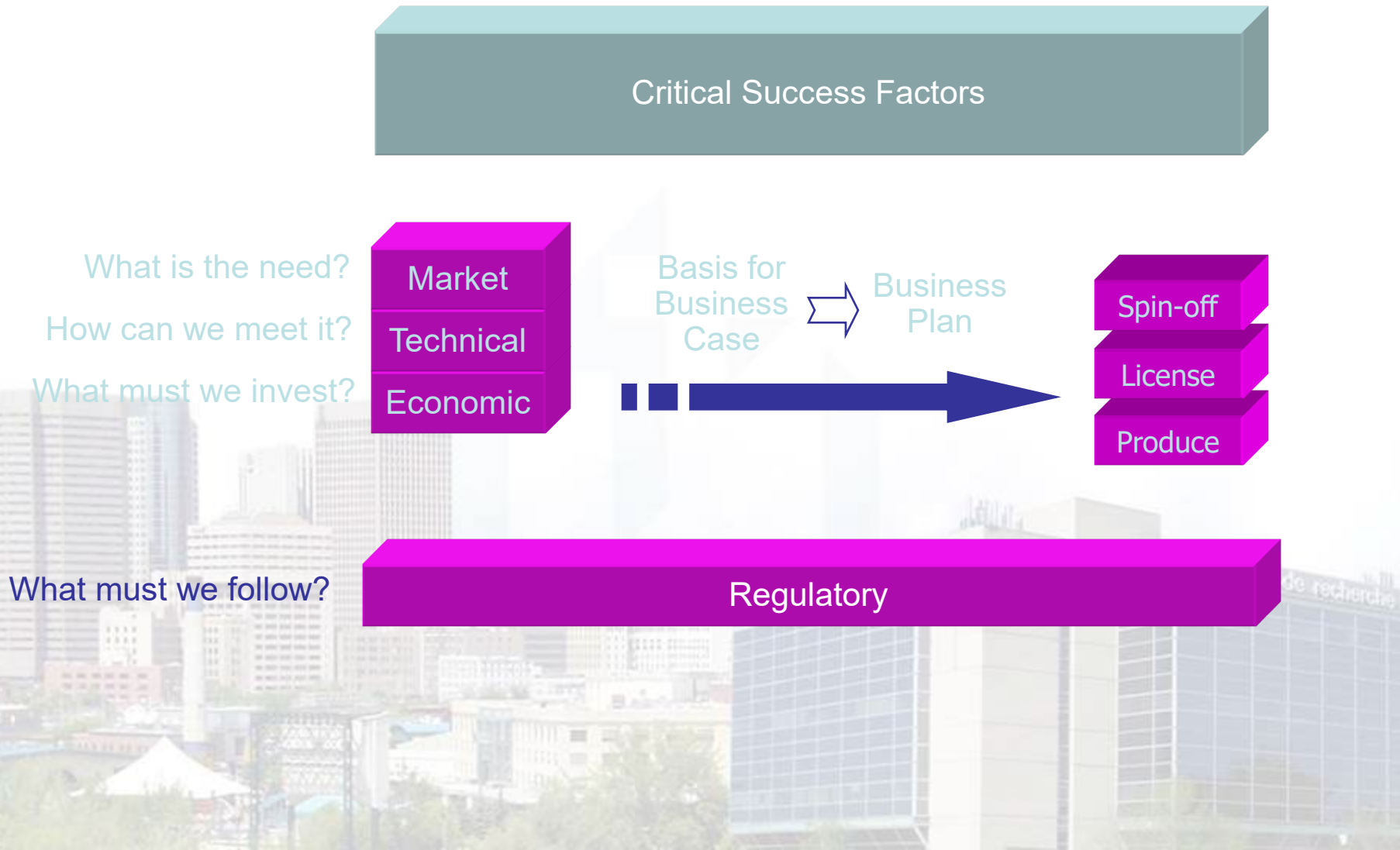
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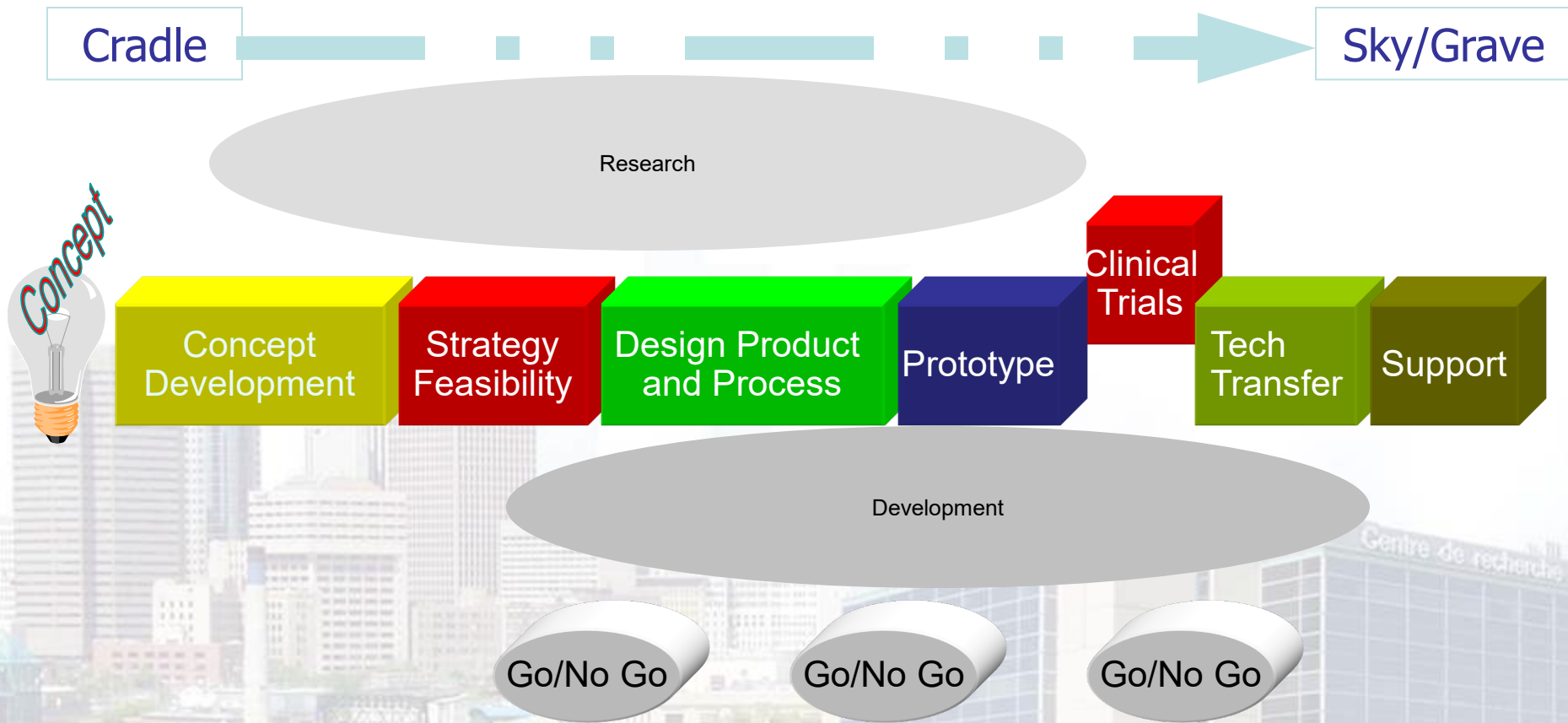
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Centre de recherche

Elements of Success



Medical Product Development



Top impediments as seen by industry

- **Access to/Recruitment of patients**
- **REB approval process**
- **Regulatory issues (approvals)**
- **Poor access to Formularies**
- **Contract delays with institution**
- **Dealing with investigators unsolicited inputs**
- **Acceptability of protocol**
- **Comparatively higher cost of Clinical Trials**
- **Knowledge of and adherence to international standards**
- **Not enough leaders & Entrepreneurs in Clinical Research**

Key Regulatory Considerations

2. **Development of a regulatory strategy
determination of path to take to gain approval.**
3. **Constant monitoring of the regulatory environment given the evolving nature of
the industry.**
4. **Gathering of evidence to prove safety, including risk analysis.**
5. **Well designed studies to prove effectiveness.**
6. **Labeling and marketing considerations.**
7. **Global registration**
8. **Manufacturing**
9. **Post Market surveillance.**