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## Life Sciences Taxonomy of Risk

Risk resides across a spectrum of internal and external areas in the Life Sciences sector and can be categorized within macro categories, such as Strategic, Operational, Regulatory or Financial.

It can also be seen as an interrelated component of a development lifecycle and seen as “opportunity” (the risks you take) and “threat” (the risks you face).

We offer below a representative cross-section of risk taxonomy from both a breakdown perspective and a life cycle perspective. This cross-section is by no means an exhaustive list and has a heavy focus on the pharmaceutical sub-sector. The taxonomy can be modified or expanded to go deeper or to incorporate unique risks specific to other sub-sectors.

We hope you will find this tool a valuable addition to your toolbox!

# MACRO Risk Categories

# Risk Sub-categories

**Strategic,  
Commercial and  
Geopolitical**

**Operational, Legal,  
Quality, Regulatory  
and Compliance**

**Financial and  
Market**

Pipeline and product portfolio	Macroeconomic and geopolitical	Pricing and access	Clinical development and/or design
Innovation	Competition	Company stakeholders and investors	
Pre-clinical or non-clinical research	Clinical development and evidence generation	Patient safety due to marketed products	Medical affairs
Manufacturing	Drug/device delivery	Commercial	IT / cybersecurity
HR / talent / organization	Regulatory / compliance	Legal	Environmental, health, & safety
Liquidity/funding	Tax	FX rates	
Market	Credit		

## Risk Category/Sub-Category

## Areas and decisions where risk can reside



# Strategic, Commercial and Geopolitical

Pipeline and product  
portfolio

Macroeconomic and  
geopolitical

Pricing and access

Clinical development  
and/or design

Innovation

Competition

Company stakeholders  
and investors

- Current and future product portfolio
- R&D Pipeline
- Target patient profile
- Clinical trial design
- Product launch strategy
- Global / local market competition and crowding
- Pricing Pressure
- Increasing role of the payor
- Government contracts / reimbursement
- Market Access
- “Volume vs. Value” decisions
- Disruptive innovation
- Competitive intelligence
- Ability to drive internal innovation
- Macro economic and political change
- Healthcare norms and sector reforms
- Mergers, acquisitions, partnerships
- External stakeholders/investor expectations
- Social media and reputational vigilance
- Internal stakeholders

## Risk Category/Sub-Category



**Operational,  
Legal, Quality,  
Regulatory and  
Compliance**

**Pre-clinical / non-clinical  
research**

**Clinical development and  
evidence generation**

**Patient safety due to  
marketed products**

**Medical Affairs**

**Manufacturing**

**Drug/device delivery**

**Commercial**

**IT / cybersecurity**

**HR / talent / organization**

**Regulatory / compliance**

**Legal**

**Environmental, health,  
and safety**

## Areas and decisions where risk can reside

- Pre-clinical operations and outcomes/evidence
- Clinical trial operations and outcomes/evidence
- Outputs align to expectations
- Third party quality and reliance – partnerships, alliances, vendors, supply chain
- Safety of trial subjects/unexpected results
- Regulatory submission uncertainty
- Labeling decisions or restrictions
- Pharmacovigilance
- Operations quality, reliability, and change control
- Business resilience and disaster recovery (BCP)
- Counterfeit medicine/illegal trade
- Cyber defense
- Communication strategy
- Data protection
- Talent attraction/retention
- Organizational change management/succession
- Health, Environment and Safety regulations
- CSR
- Reputational impact of operational decisions
- Bribery, corruption
- IP, FTO and patent expiry
- Litigation

## Risk Category/Sub-Category



Liquidity/funding

Tax

FX rates

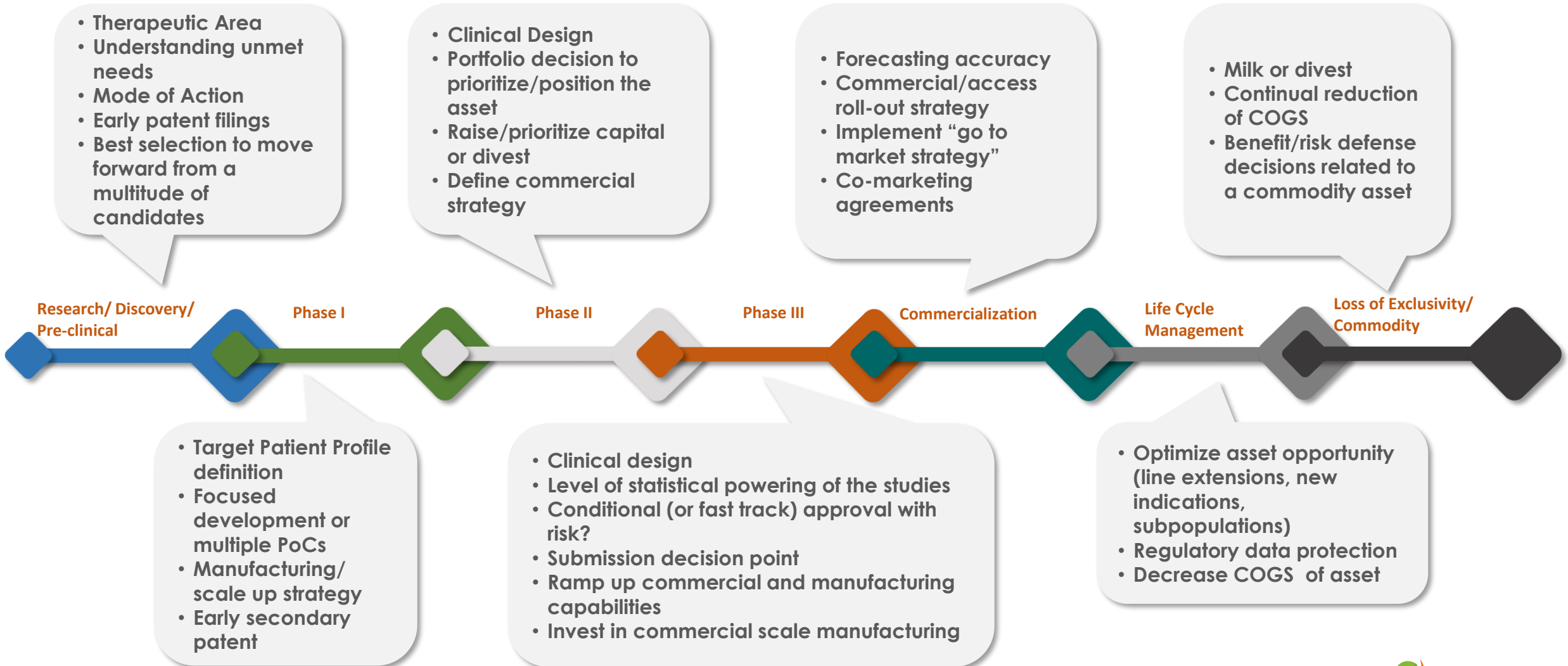
Credit

Market

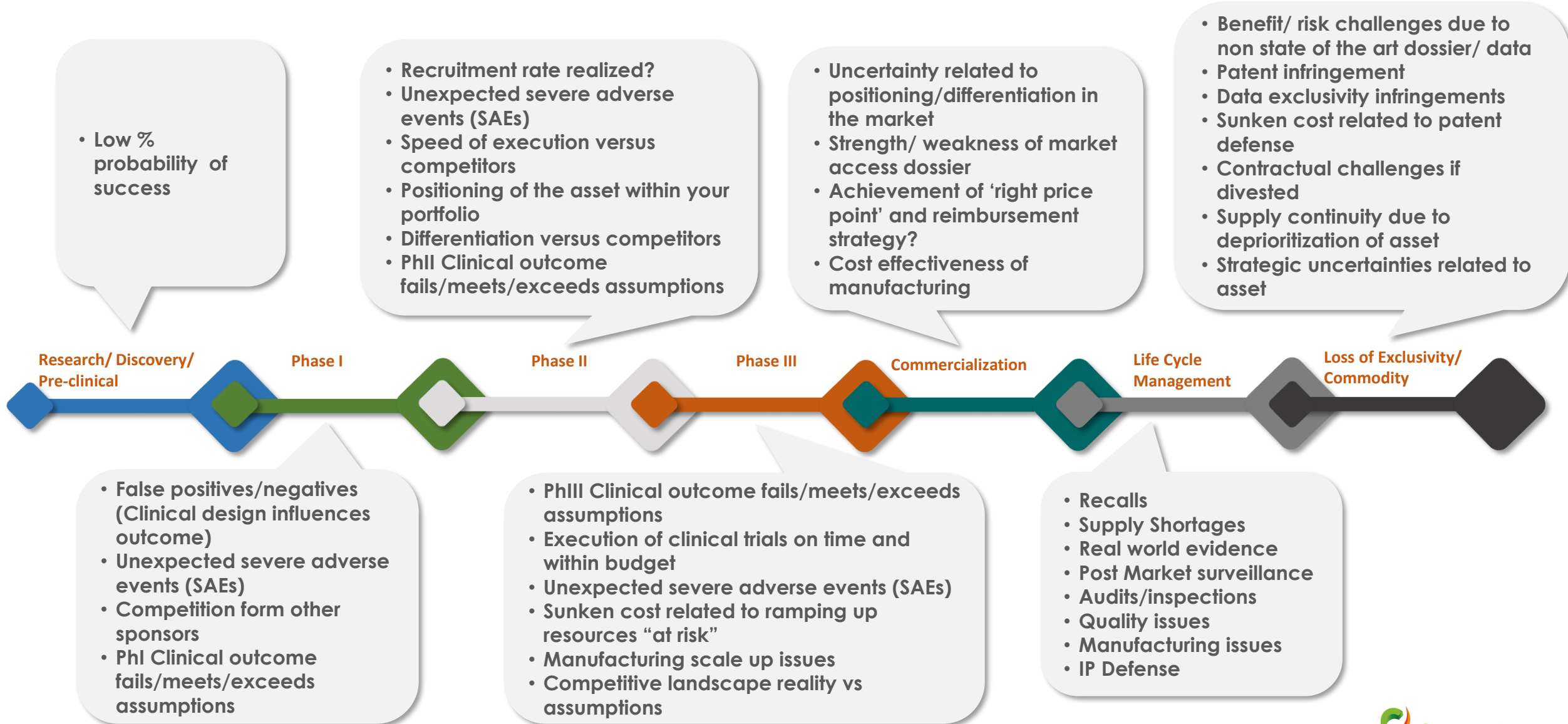
## Areas and decisions where risk can reside

- Input prices
- Equity prices
- Corporate investments
- Cash flow
- Currency and interest rate fluctuations
- Profit & loss
- Credit, debt
- Pension obligations
- Funding
- Venture capital relationships
- Changing tax laws
- Changing import/export laws

# The “Risk you Take” – an Example from Pharma



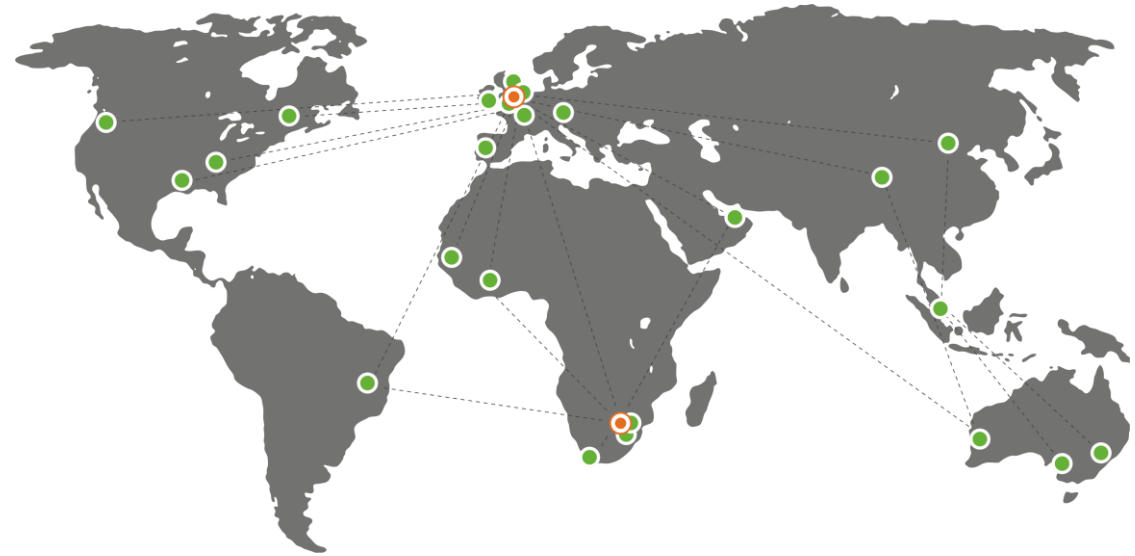
# The “Risk you Face” – an Example from Pharma





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