



Club Founder
Dr. Mahmoud Bahgat



International Business Development Club

Licensing in Pharma Tips & Tricks

Wednesday 17th July 2024
10pm KSA EGY 11pm UAE



Co-Founder & Host:
Dr. Mahmoud Ezzat



Dr. Mohamed El Shafei
Business Development Manager
Sandoz- Egypt

Disclaimer

- **The views expressed herein are those of the presenter Not related to any organization**
- **No Confidential data**



ABOUT OUR SPEAKER

"Ambition is Enthusiasm with a Purpose".

- ***Experienced Business Development Manager with +14 years' experience in the pharmaceuticals industry.***
- ***Skilled in Business Development, licensing, Acquisition, Marketing and Product Management***
- ***Bachelor's degree in pharmaceutical sciences.***
- ***Master degree in strategic management.***
- ***Worked for Hikma pharmaceuticals for +11 years with several roles in sales , marketing & business development.***
- ***Worked in Sandoz as a business development manager.***



Dr. Mohamed Elshafei
Business Development Manager

Agenda

- Licensing Core **Fundamentals**
- DB **Duties** and **Responsibilities**
- Licensing Road Map & Process: **Hands on Experiences**
- **Tips and Tricks** in Licensing
- Conclusion



Agenda



Licensing Core Fundamentals

Market Size and Figures

Regulatory Strategies

Patents Vs. exclusivity

R&D Process

Product : Life Cycle Management

Patent life Extension

Licensing Process

Types of deals

Forecasting models

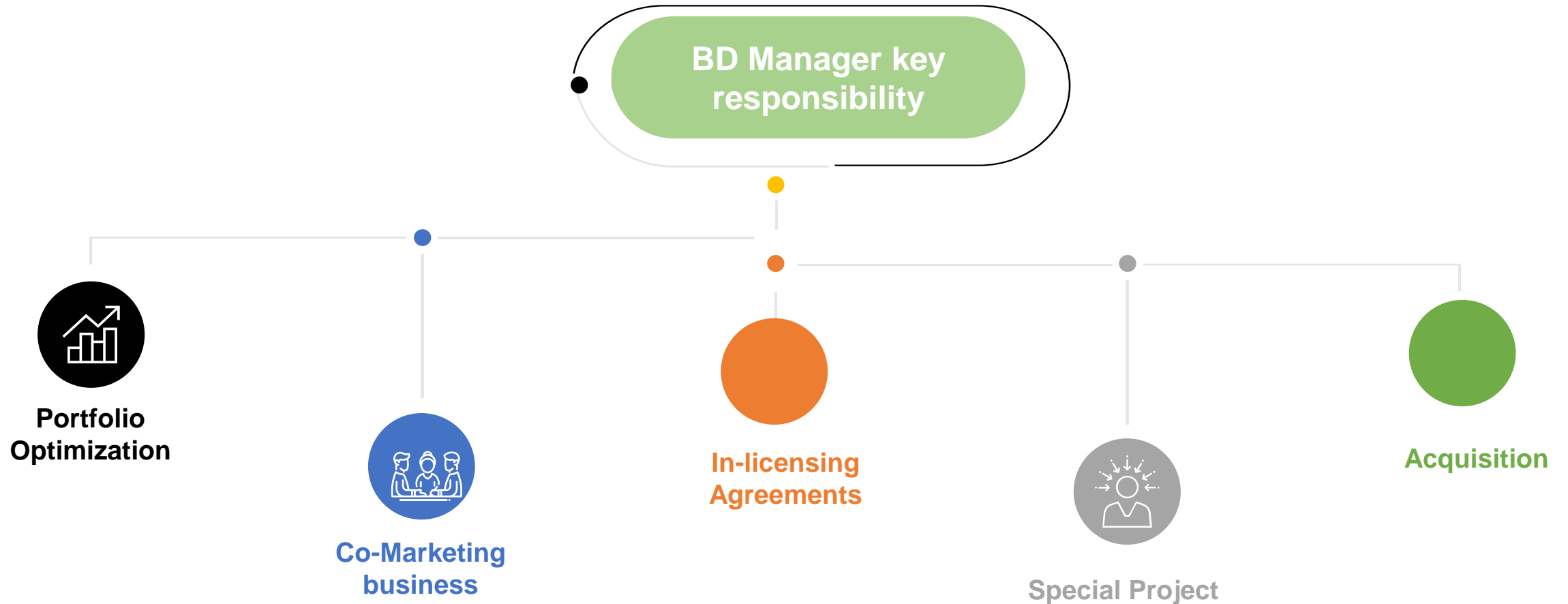
Patent Cliff

Data Exclusivity and Market Protection

Financial Modeling



Business Development as an arm of any corporation



Business Development Department duties

1. Responsible for supporting business development
 - Projects
 - Strategic initiatives



Business Development Department duties

2. Be part of the

Strategic planning process

and involved in the preparation of long-range strategies and action plans



Business Development Department duties

3.Scout for

- New portfolio
- business development opportunities

that are in line with the strategic plan outlined for the region



Business Development Department duties

4.Track and analyze

- Industry trends,
- Market
- Competitor events and
- Changes in health care reforms

that will impact country strategies, business development priorities and market forecasts



Business Development Department duties

5. Conduct

- Detailed market analyses
- Dedicated research including,
 - Assessing the potential of new products,
 - Preparing business cases and
 - Supporting their presentation to management team

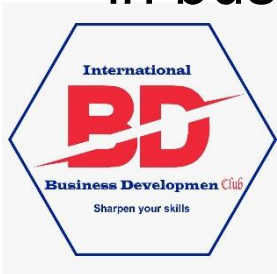


Business Development Department duties

6. Ensure

- Successful coordination of different functions
 - Marketing
 - Sales
 - R&D
 - Operations
 - IT
 - Medical
 - Legal

in business development and strategic projects



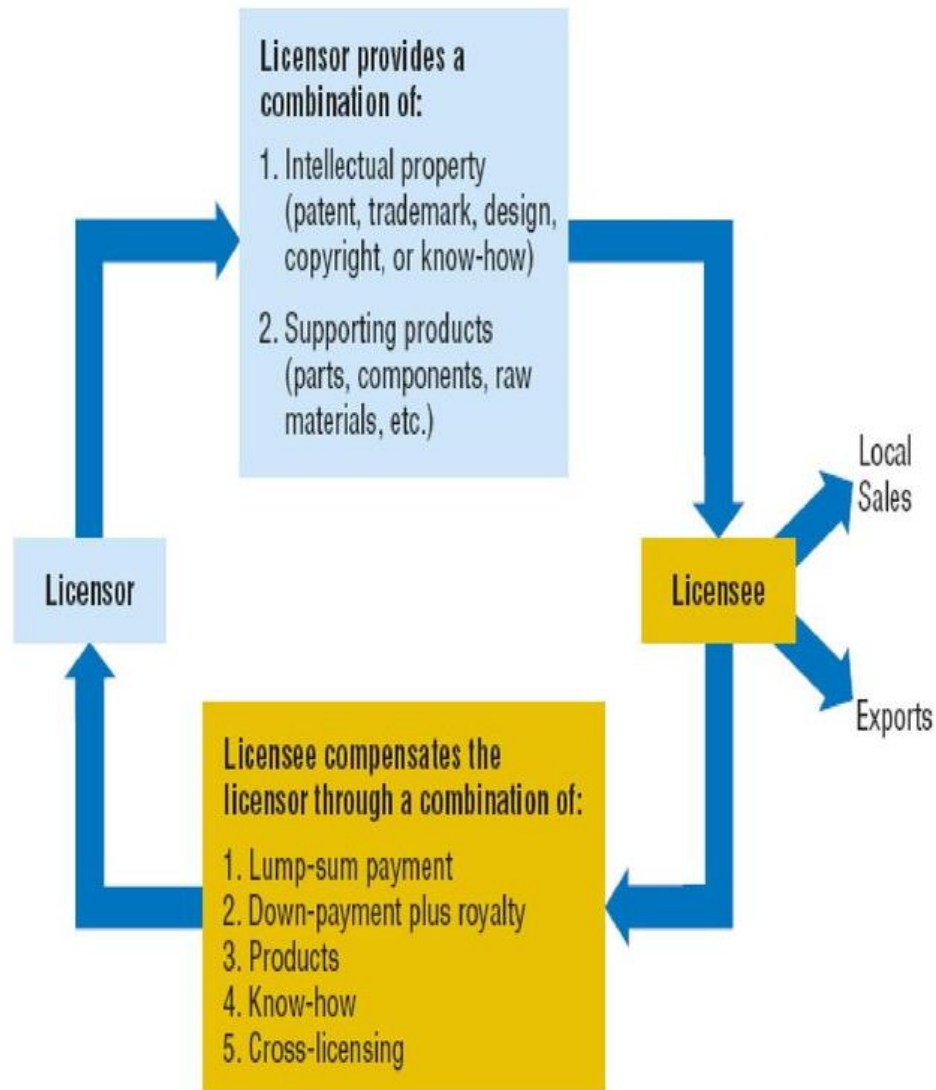
Business Development Department duties

7. Ensure

- Compliance with
 - Relevant Acts
 - legal demands
 - Ethical standards
 - Corporate Business
 - Safety Procedures
 - Code of Business Conduct.



Licensor / licensee relationship



Licensing as a Foreign Market Entry Strategy

SOURCE: Adapted from Welch and Welch (1996) and personal correspondence with Lawrence Welch.

Example of the top licensing deals

1. AstraZeneca/Daiichi Sankyo

Licensors: Daiichi Sankyo

Licensee: AstraZeneca

Deal size: \$6.0 billion

Upfront: \$1.0 billion

Asset: TROP2-targeted antibody-drug conjugate datopotamab deruxtecan for lung, breast and other cancers



[Daiichi Sankyo and AstraZeneca Enter New Global Development and Commercialization Collaboration for Daiichi Sankyo's ADC DS-1062 - Press Releases - Media - Daiichi Sankyo](#)

Example of the top licensing deals

2. AbbVie/Genmab

Licensor: Genmab

Licensee: AbbVie

Deal size: \$3.9 billion

Upfront: \$750 million

Assets: Multiple bispecific antibodies for cancer



sec.gov/Archives/edgar/data/1434265/000155837020010409/gmab-20200630ex9919a1b8d.htm
[AbbVie And Genmab Announce Broad Oncology Collaboration | Reuters](#)

Licensor / licensee relationship

▲ From the perspective of the licensor:

1. A firm lacks the capital, managerial resources, or knowledge of foreign markets required for exporting or FDI, but it wants to earn additional profits with minimal commitment.
2. Licensing is a way of testing and proactively developing a market that can later be exploited by direct investment.
3. The technology involved is not central to the licensor's core business. Not surprisingly, single-or dominant-product firms are very reluctant to license their core technology, whereas diversified firms are much more willing to license peripheral technologies.

Licensor / licensee relationship

▲ From the perspective of the licensee:

- The main advantage of licensing is that the licensee's existing products or technology can be acquired more cheaply, faster, and with less risk from third parties (licensors) than by internal R&D.
- Another advantage is that the licensee can gain product designs for a desired diversification, to complement other assets it possesses such as **production** or **marketing capability**.

Licensing Types

In-licensing

Out-licensing

Patent licensing

Technology licensing

Non-exclusive licensing

Field of use licensing

Territory licensing

Sublicensing

Co-development and co-promotion agreements

Collaborative research and development agreements



[Guide to Life Sciences Licensing Agreements \(excedr.com\)](http://excedr.com)

Licensing Types

Early In-Licensing:

- Licensing in IP from a 3rd party .Development might have started, but dossier not available for due diligence yet.

Late In-Licensing:

- Licensing in IP from a 3rd party). Development is completed and dossier is available

Adapted from

[Licensing early-versus late-stage technologies: The licensee perspective – ScienceDirect Q2 2023 Biopharma Licensing and Venture Report \(jpmorgan.com\)](#)



Licensing Types

Territory Extension:

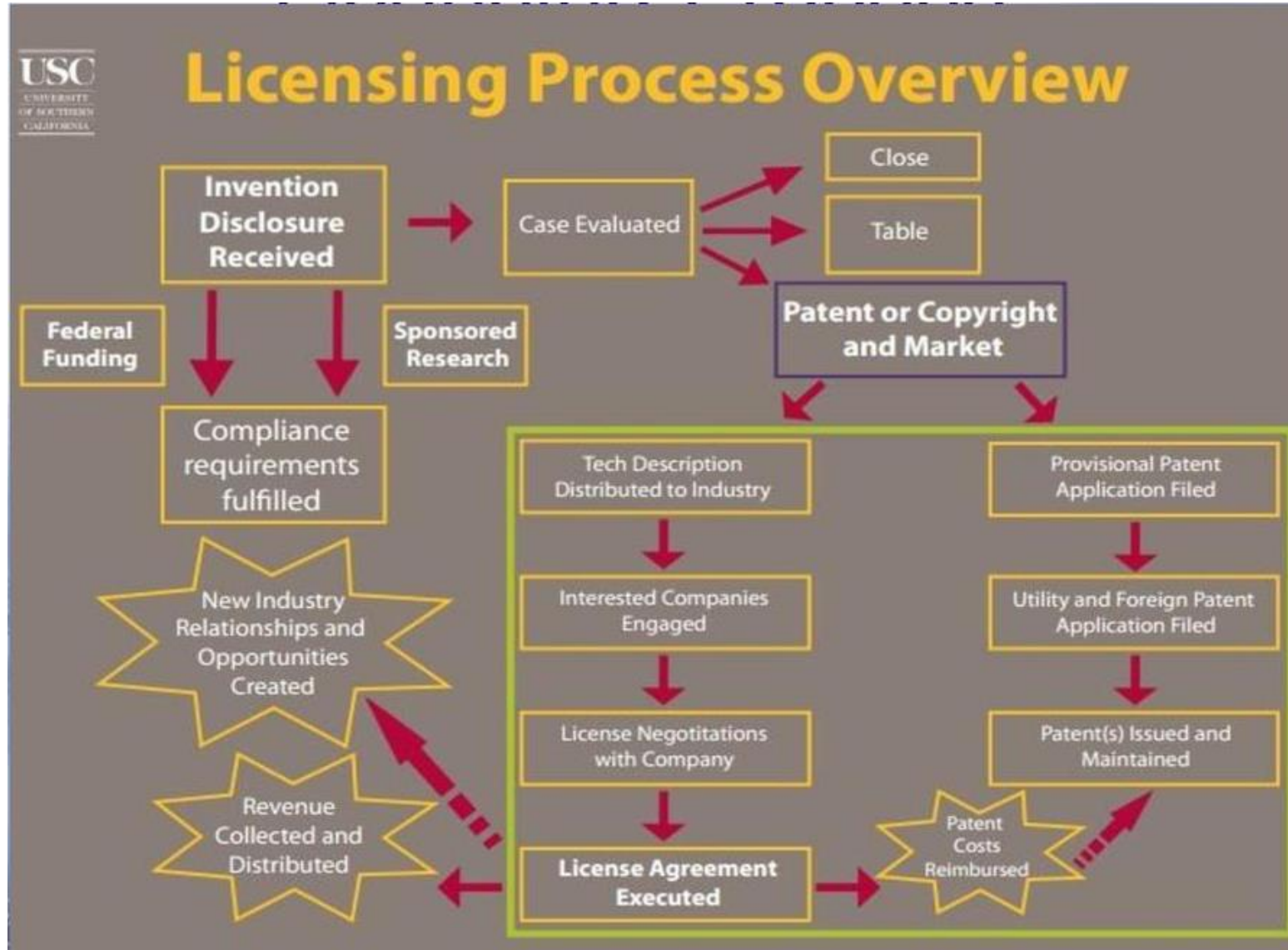
An existing Agreement is amended by additional territories/Regions .

Line Extension:

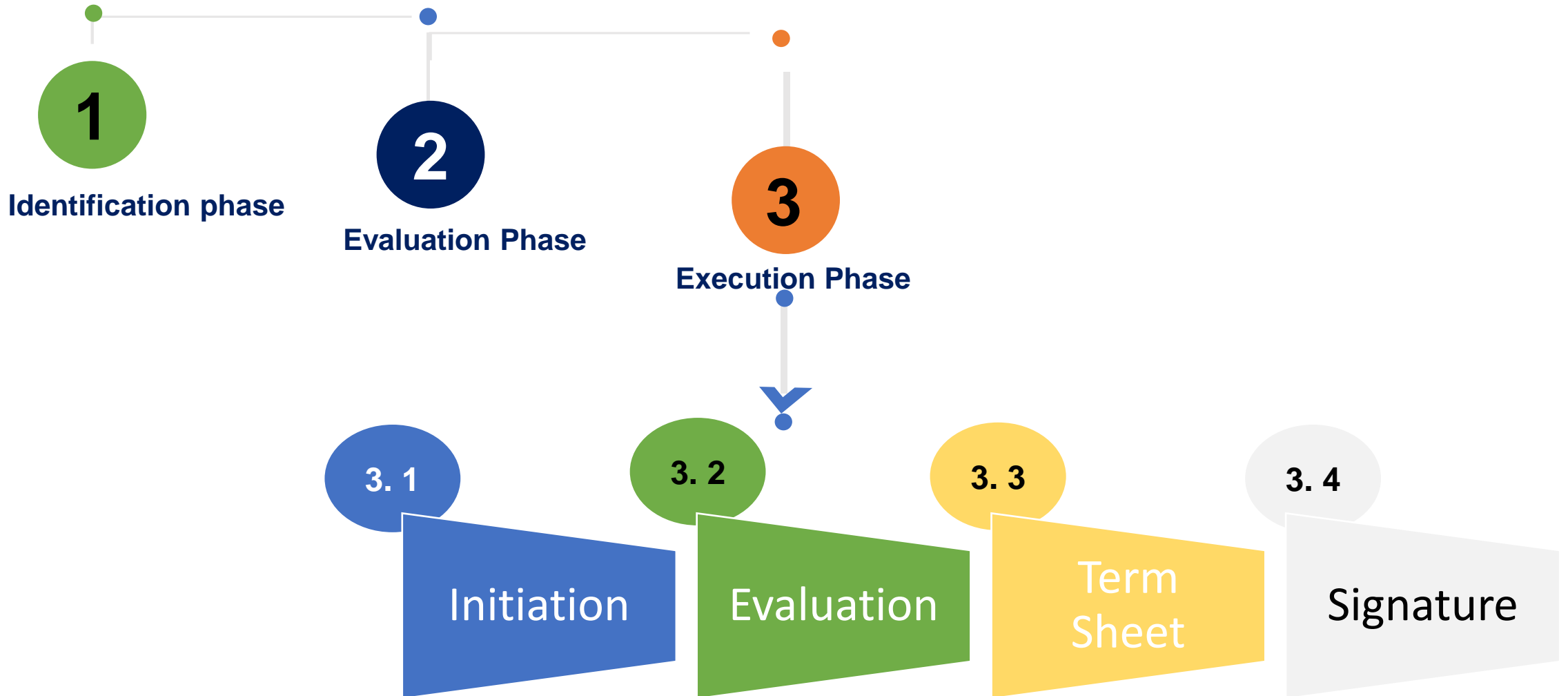
- An existing Agreement is amended by Strengths, dosage forms.... etc.



Process Overview



Pharma Licensing Roadmap and Process : Regional Flavor



Three-step approach to annual planning / Portfolio workshops....

■ Step 1: Product Identification

- Develop search criteria/filters
- Identify and search databases
- Analyse results
- Recommend a preliminary list
- Work shops
- Team member idea
- Vision Board per therapy area
- Wish list (workshops)
- Specialty (Portfolio Gap)

RX

IQVIA Sales

FDA

BI

Please check the Chat after the meeting for supportive materials



Three-step approach to annual planning / Portfolio workshops....

- **Step 2: Product Evaluation**

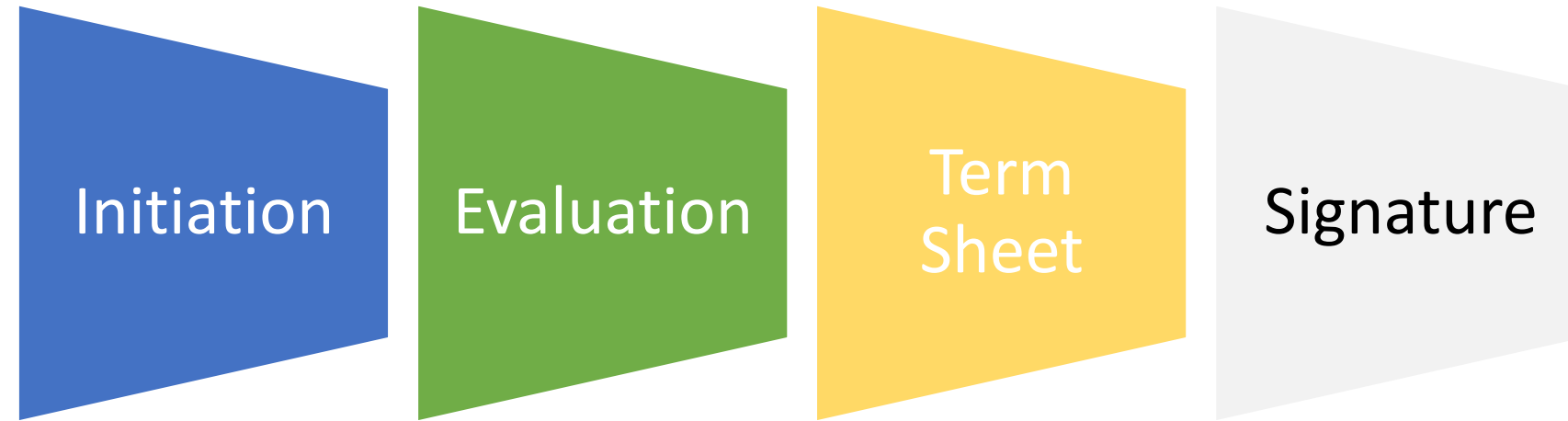


Three-step approach to annual planning / Portfolio workshops....

- **Step 3: Execution & Implementation**
 - Identify company targets
 - Develop a 5-yrs , L+5 execution plan ...etc.
 - Create an Implementation plan



Dossier /Product Licensing Steps



- Initiating contact with target company/product
- If interested, **NDA** is signed

Disclosure Agreement

- ❑ Time limit of **xxxx** years
- ❑ No limitation on disclosures to others



Dossier /Product Licensing Steps

Initiation

Evaluation

Term
Sheet

Signature

- Finalizing the market study and Due diligence by:



DUE DILIGENCE:

A hand in a blue plaid shirt sleeve points at a glowing blue circular interface. The interface features concentric circles, dashed lines, and small white dots. The words "DUE DILIGENCE" are written in a bold, white, sans-serif font in the center of the circle. A bright blue light flare emanates from the text. The background is dark with some blurred light effects.

**DUE
DILIGENCE**

Checklist for contract due diligence

RA

QA

Operation

R&D

SC

Finance

Procurement

TAX

Commercial

Accordingly, to the business development deal the mapping will be reshaped



Dossier /Product Licensing Steps

Initiation

Evaluation

Term
Sheet

Signature

- Exchanging preliminary financial terms between two Parts
- Evaluating feasibility of the project
- Negotiating with the 2nd part to reach agreeable terms for both parties
- Go/No Go decision

Dossier /Product Licensing Steps

Initiation

Evaluation

Term Sheet

Signature

- Review the agreement
- Final draft
- Signature
- Internal Kick-off then hand over to Portfolio/
New launch manager team



Key Factors to Consider in Pharma Licensing

Successful pharma licensing collaborations require careful consideration of several key factors.

- By defining **clear objectives**
- **Aligning interests**
- Leveraging complementary **skills and resources**,
- Establishing a robust **IP framework**
- Addressing **financial arrangements**
- Aligning **regulatory and commercialization strategies**, and planning for potential termination or disputes,



Collaborations can overcome challenges and maximize the potential for success.

References and Potential links

- [Evaluating a Potential Licensee: 5 Steps - IMC Licensing](#)
 - [\(6\) Pharma \(In/Out\) Licensing Framework: Approach, Model and Factors Affecting Valuation | LinkedIn](#)
 - [Evaluating a Potential Licensee: 5 Steps - IMC Licensing](#)
 - [Why In-Licensing in Pharma? - Blog \(pharmavenue.com\)](#)
 - [Courses for Pharma Business Development & Licensing \(celforpharma.com\)](#)
 - [Pharma Licensing Deal Structures: A Complete Guide - Blog \(pharmavenue.com\)](#)
 - [Pharma Industry News and Analysis | FirstWord Pharma](#)
 - [Key Steps & Best Practices In Pharma In-Licensing | Credevo Articles](#)
 - [Guide to Life Sciences Licensing Agreements \(excedr.com\)](#)
 - [AbbVie And Genmab Announce Broad Oncology Collaboration | Reuters](#)
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- [CPHI Online - A marketplace for pharma companies, products and industry news \(cphi-online.com\)](#)
 - [FDA Approved Drugs | CenterWatch](#)





Thank You