



Due Diligence

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Due Diligence Envisions a Future

What would
we do with this
opportunity?

How should we
structure a
deal?

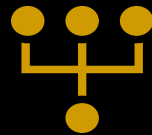
Outline



Efficient diligence needed



Diligence should reflect the purposes



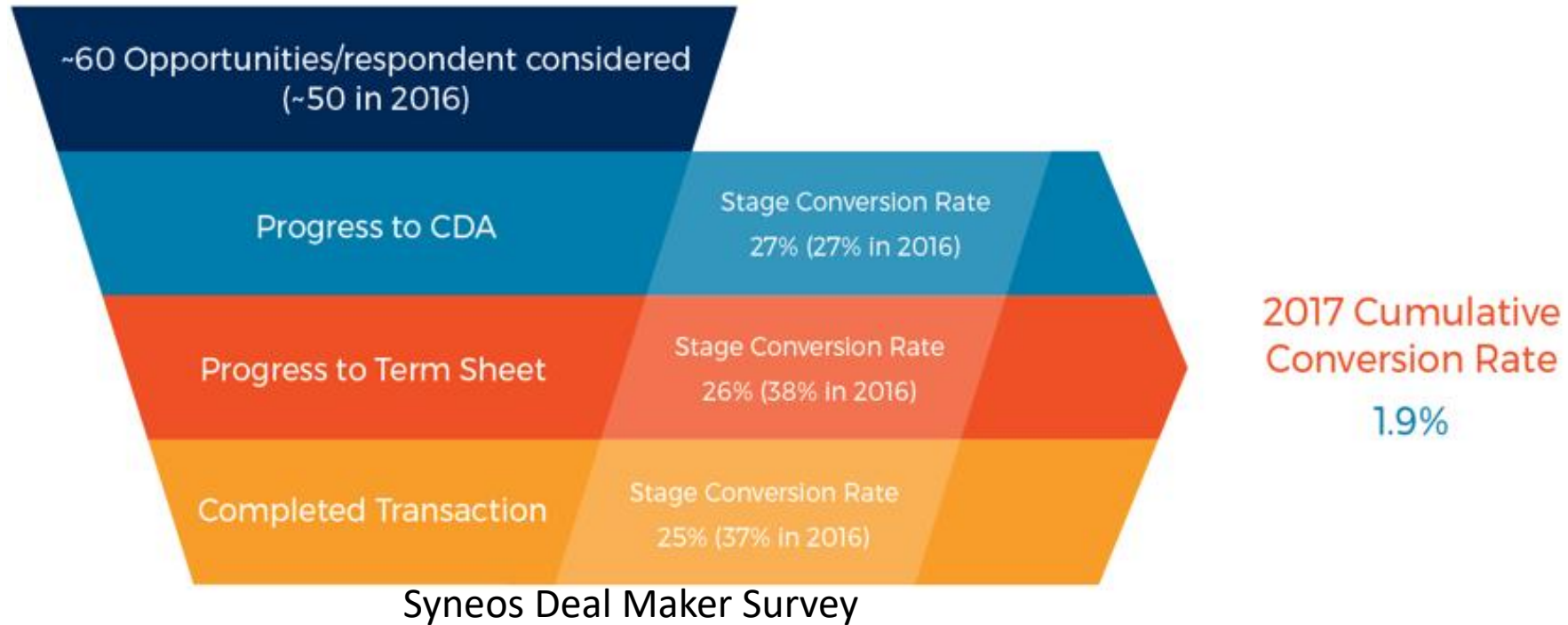
The Due Diligence Process



How to help your team

LOA means need Efficient Diligence





Deal triage means need Diligence Efficiency

Thus Efficient Diligence is Needed



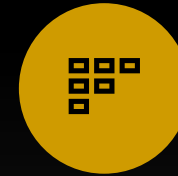
Due Diligence Should Reflect the Purposes



Confirm what you believe



Identify risks and deal killers



Plan for development



Get commitment for resources



Understand capabilities of partner for contributions



Understand deal structure



Drive reps and warranties



Establish value

The Due Diligence Process

Before Due Diligence

Diligence Team Formation

Checklists

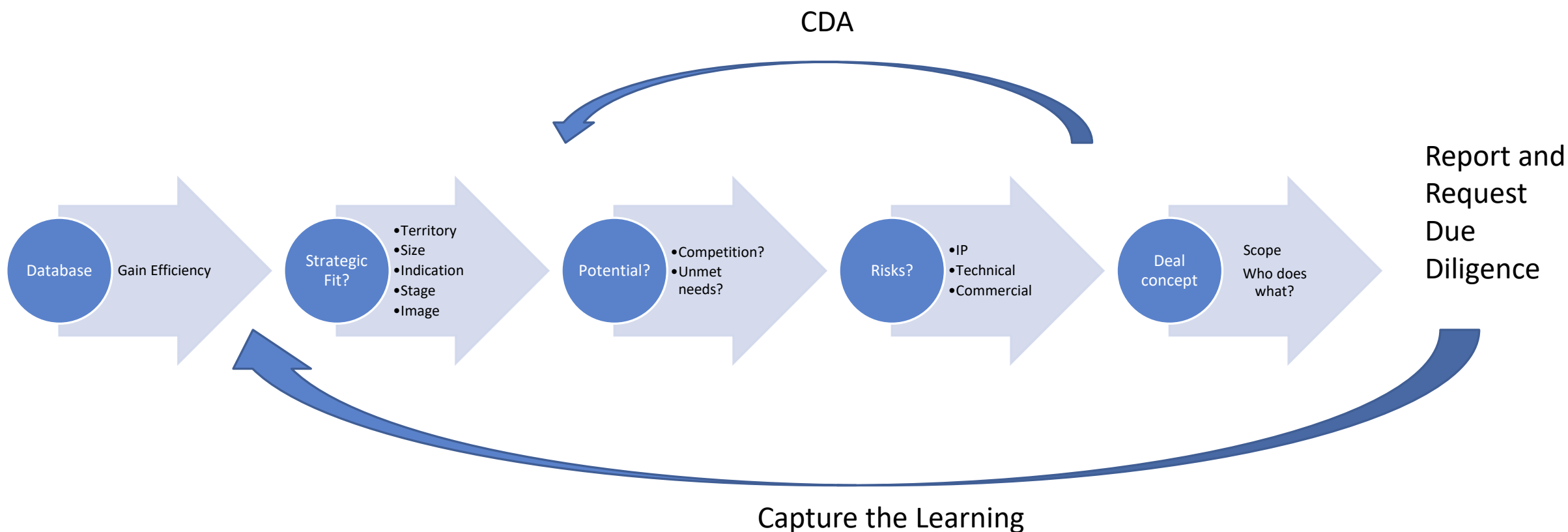
Information request

Staged assessment

Report

Share the lessons

Before Due Diligence – Team Evaluation



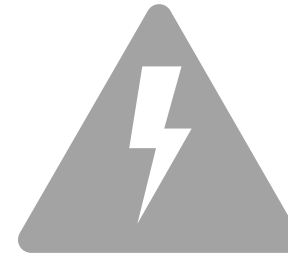
Strategic Fit is the First Filter



A simple written strategy

everyone can refer to it

stops repeated discussions on opportunities that won't gather the needed support to advance.



A “NO” List = things that can be eliminated unreviewed

The Big Questions for Evaluations

Is this a strategic fit for us?

Image, Scale, Expertise, stage, Sales Force, Revenue Needs

rNPV=
Today's Value

What is the potential?

Future revenue cash flows =
((price x patient) – sales costs- cogs)

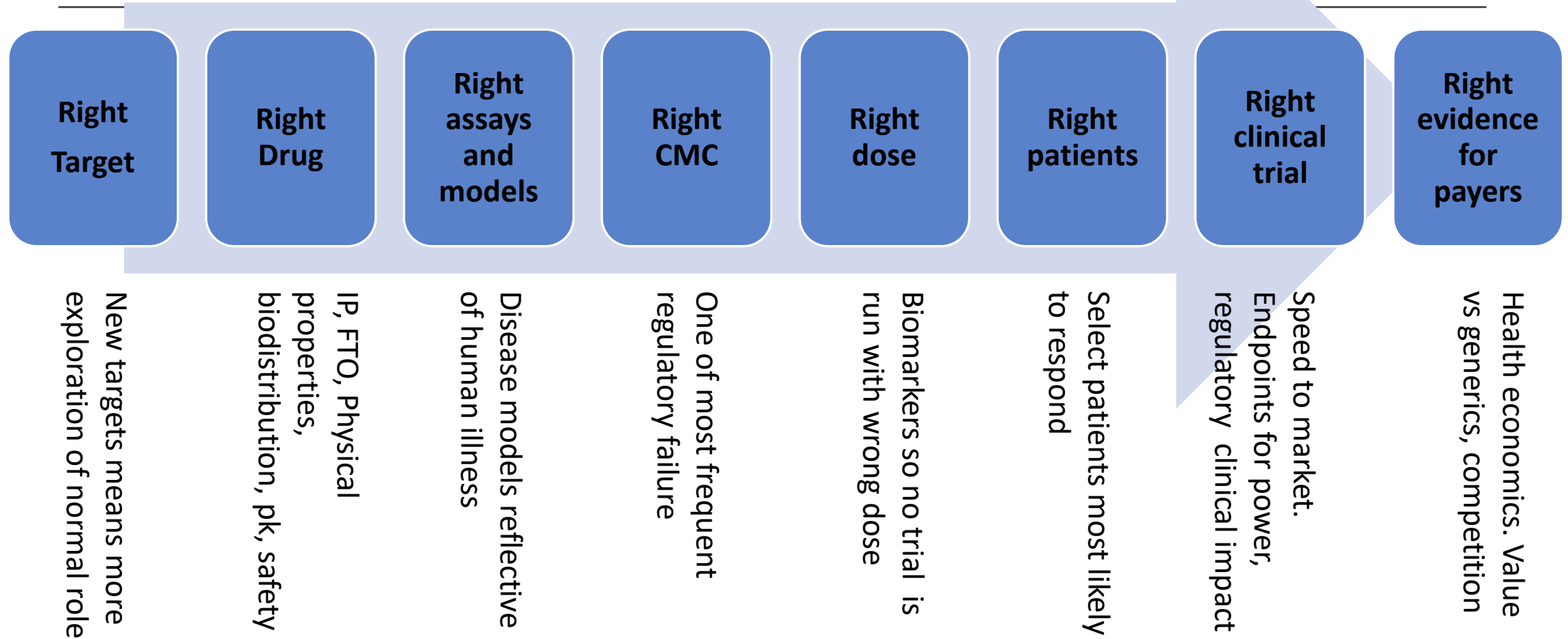
What do we spend (time and money) to get that potential?

Minus costs over time

What are the risks and how can they be addressed?

Adjusted for risks

Identify the risks for diligence



Variations in Evaluation before Due diligence

TPP	Write a TPP – mock label with indication, population, competition, drug properties, etc.
Include?	<p>Evaluation can include assessment:</p> <ul style="list-style-type: none">•How registerable (regulatory)•Commercial feedback on TPP•Reimbursement on endpoints
Terms?	<p>If must do a term sheet before formal due diligence</p> <ul style="list-style-type: none">•More team members•More senior management review•More involvement commercial and finance

BD TPP – evolving label + strategic framework

- Opportunity description
 - Drug, Company, Molecule Type, Mechanism, Stage, Indications
- Strategic Fit
- Rationale for Patient Value
 - differentiation & competitive position
- Target validation
- Efficacy Summary
 - Available data, Indication, Endpoints, Population, Route, PK, Treatment Regimen
- Safety Summary
 - Available data, clinical and non-clinical safety, drug interactions, precautions, contraindications
- Formulation (storage and handling)
- Evaluation of manufacturing
- IP position
- Development plans & timelines
- Valuation
- Factors for success
- Risk Factors and mitigation plans

Evaluation Report – Request for Due Diligence

Should include

- Team members and their roles
- Strategic fit assessment
- Potential and differentiation
- Risks identified
- Deal concept – scope, deal type, what the partner role will be
- Requests for team members

The Due Diligence Process



Diligence Team
Formation



Checklists



Information
request



Staged
assessment



Report



Share the
lessons

Diligence Team Formation



Selected for expertise in disciplines, credibility with senior management

Start with focus where risks identified, expand team if these risks not deal killers



Core Team can Build over time

GATE KEEPER & Team Leader

Preclinical

biology, chemistry, tox, GLP compliance, PK/ADME

Clinical

clin pharm, development, safety, regulatory, statistics, GCP compliance

Manufacturing

process dev, quality, CMC regulatory, manufacturing

Commercial

market research, medical affairs

Legal

IP and contracts

Finance

valuation, resourcing

BIGGER for later stage – more data, less time to solve risks



Briefed with Evaluation Report, process, checklists

External consultants?



WHEN THERE IS INSUFFICIENT
EXPERTISE



AS AN INDEPENDENT VOICE OR
2ND OPINION



WHEN THERE IS SENSITIVE
INFORMATION OR POTENTIAL
TAINT

Checklists

Questions for each discipline

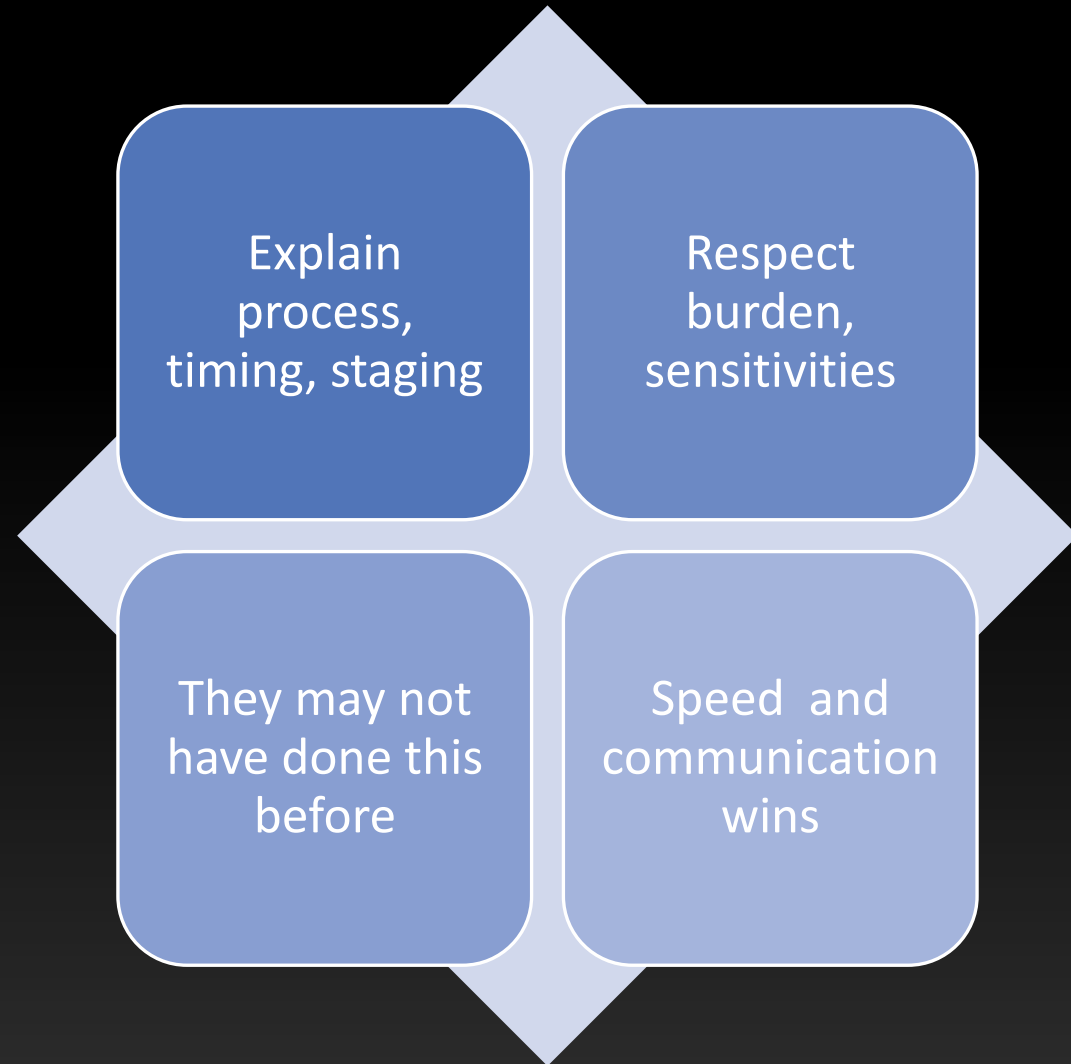
- ***In vitro data***

- Is there identification of target expression on various human cell types in vitro?
- What is the binding (K_d) of the product to the target?
- Have the biological effects of binding to the target been characterized?
- In the case of a monoclonal antibody, has the antigen recognized by the monoclonal been well characterized and its expression on various cell types been identified?
- What is the species specificity of binding?
- Is a bioassay available?

Each discipline asked for summary of data and assessment

Should identify any deal killers and risks to be addressed

Information Request



Example Information Requests

Discovery

- All reports of any pharmacology studies undertaken

Toxicology

- Status and findings of reproductive toxicology studies
- hERG testing
- Plans for carcinogenicity testing
- Records of discussions with regulatory authorities

Chemical Pharmaceutical Development

- Synthetic Pathways
- Structural Elucidation
 - ♦ NMR
 - ♦ Mass Spec
 - ♦ UV-Visible Spectroscopy

Physicochemical Characterization

- ♦ Ionization constant
- ♦ Polymorphism
- ♦ Crystal Habit
- ♦ Solubility Profile

Clinical R&D

- Copies of all clinical protocols including amendments
- Clinical Study Reports
- Clinical Data Reports
- Clinical Development Plans
- Case report forms should be available or retrievable for review
- Minutes from advisory boards or expert panels

1st step of Staged assessment



Add Team members

Research

Clinical development

Clinical pharmacology

Clinical operations

Regulatory

Commercial (may include reimbursement)

Finance

CMC and manufacturing

Quality

Tox and TK

PK and Metabolism

Biostats

Legal (IP and contracts)

Separate Diligence Streams – Sensitive!



Molecule structures – often use a 3rd party assessment before term sheet agreed

- Can use named individuals in confidentiality agreement



IP- IP attorney to IP attorney

- Don't expect to get FTO opinion
- Identify all owned and/or licensed patents and applications, along with their status and correspondence to products.
- Is the company aware of any information that can make them unpatentable, invalid, or unenforceable?
- Ask for documentation that the Company owns these patents or has licensed rights.
- Is the Company aware of any third-party patents or applications that may be infringed, has the Company received a notice from a third-party, or obtained a formal or informal opinion from counsel in the past?
- Has the Company been involved in or anticipates any IP-related dispute?
- What can be done to improve the position?



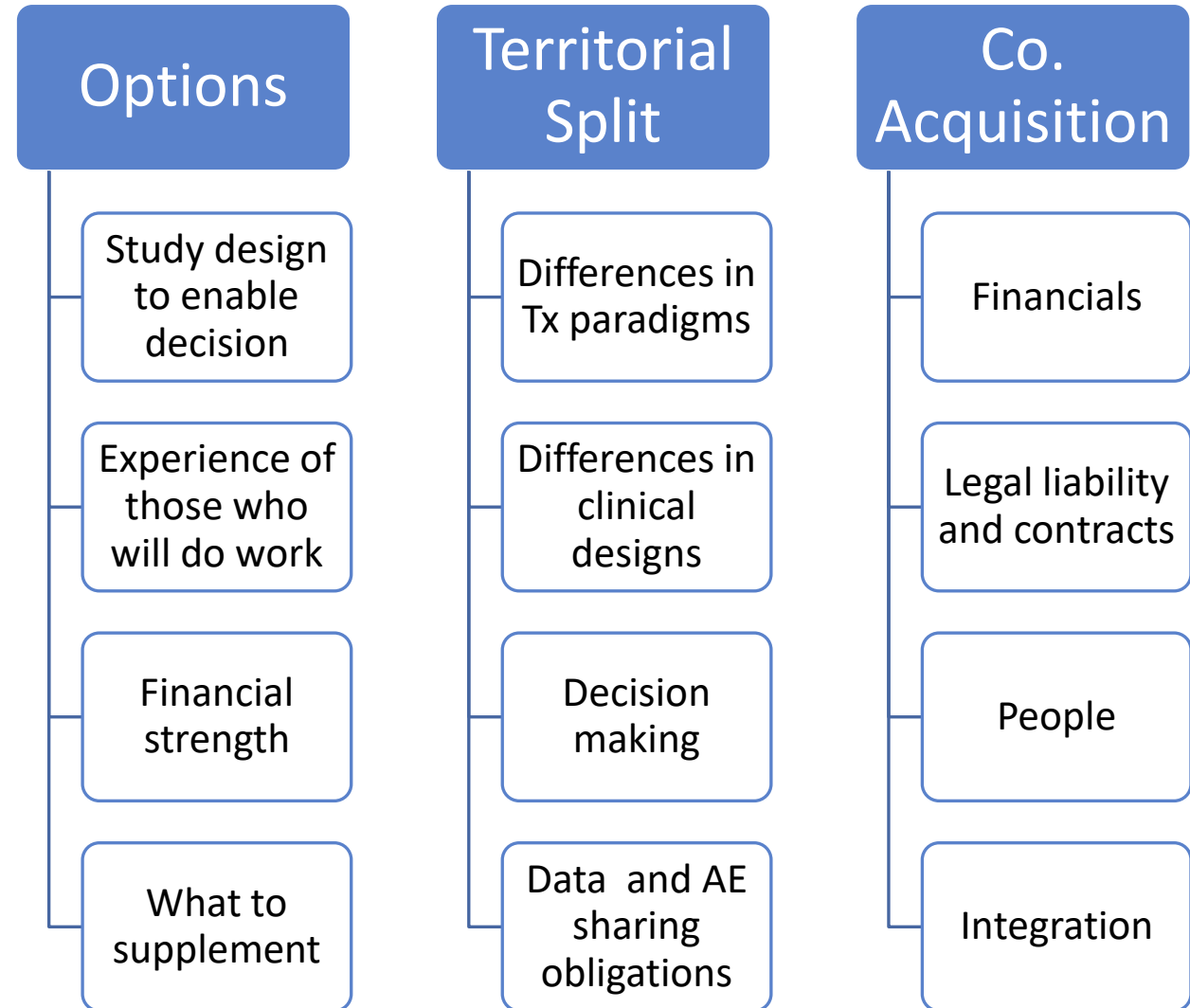
Contracts

- Look at assignment of IP for consultants and employees
- Look at pre-existing licensing obligations (redacted for financials)



Manufacturing trade secrets

Structure Dependent Diligence



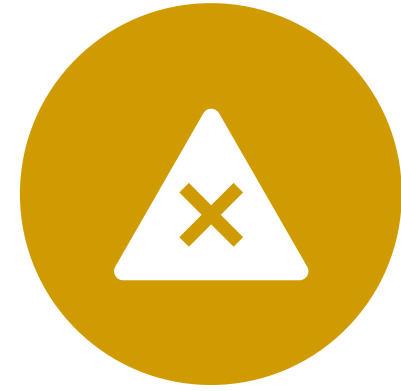
If negotiating in parallel, need to understand



EXPECTED DEAL
STRUCTURE



VALUE DRIVERS



RISKS AND WHEN THEY
WILL BE ADDRESSED

Feedback to partner



Process, Status, timelines



Deal concept – option or license or acquisition



Scope (backups, exclusivities, non-competes)



Value drivers (assumptions in models)



Risks identified – allow them to talk about their plans for mitigation



Development plans – aligning the partnership



Capabilities & Value Added – you are selling them too

Internal Alignment



- Team to align on risks and potential



- Create a development plan



- Estimate costs and resources



- Report to Senior Management

Diligence report structure

Executive Summary

- Opportunity description
- Strategic fit
- Potential
- Risks and their mitigation
- Development plan
- Recommendation for Deal structure – roles, value drivers

Reports of each functional representative

They are judging you

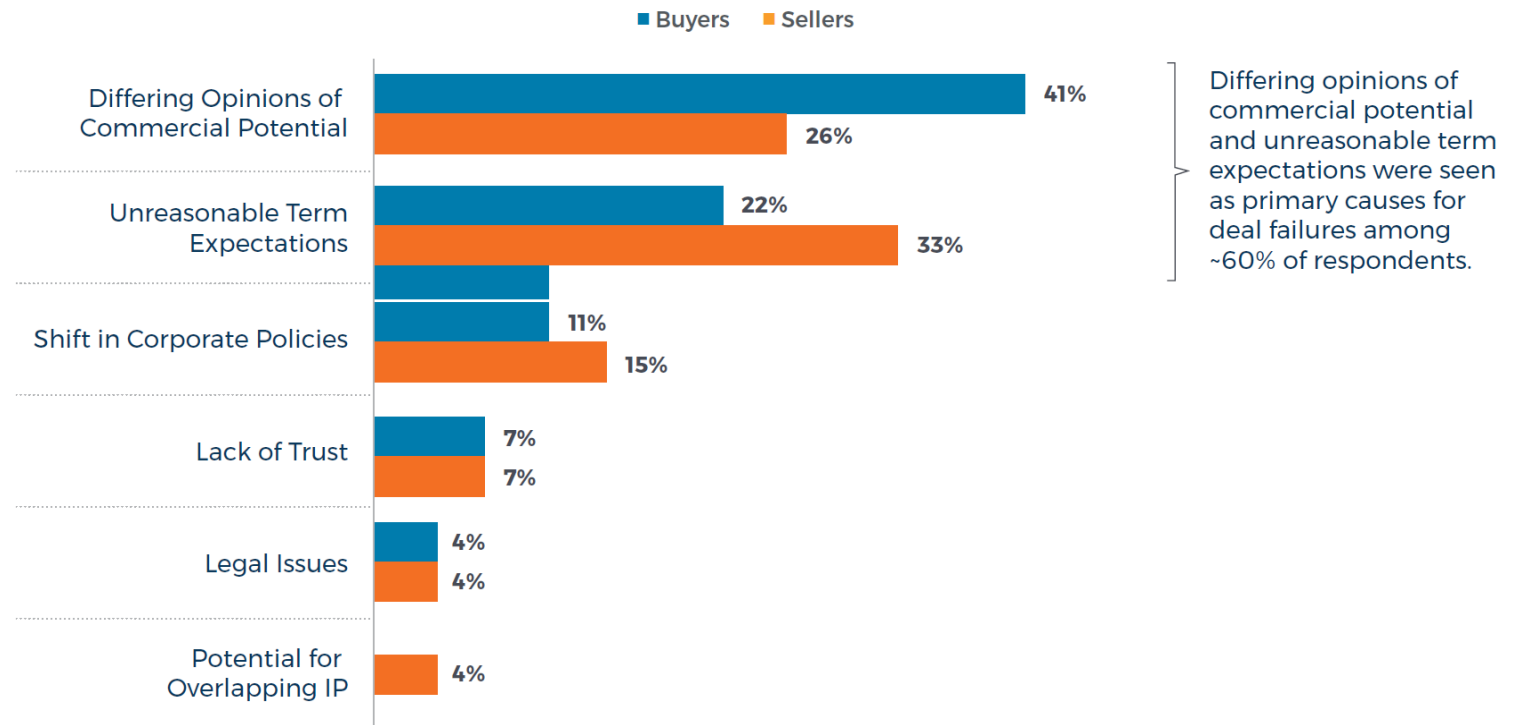
- How interested are you?
- How experienced are you?
- Are you interested in more than 1 indication?
- Will you be diligent in the development?
- How fast are you?
- Can we align on the assumptions?
- Are you trustworthy?

**Your company
reputation lasts
and spreads**

Where most deals fail

Buyers and sellers report similar pitfalls for failed deals, with Buyers citing differing opinions of an asset's commercial potential and sellers citing unreasonable term expectations as the major factors.

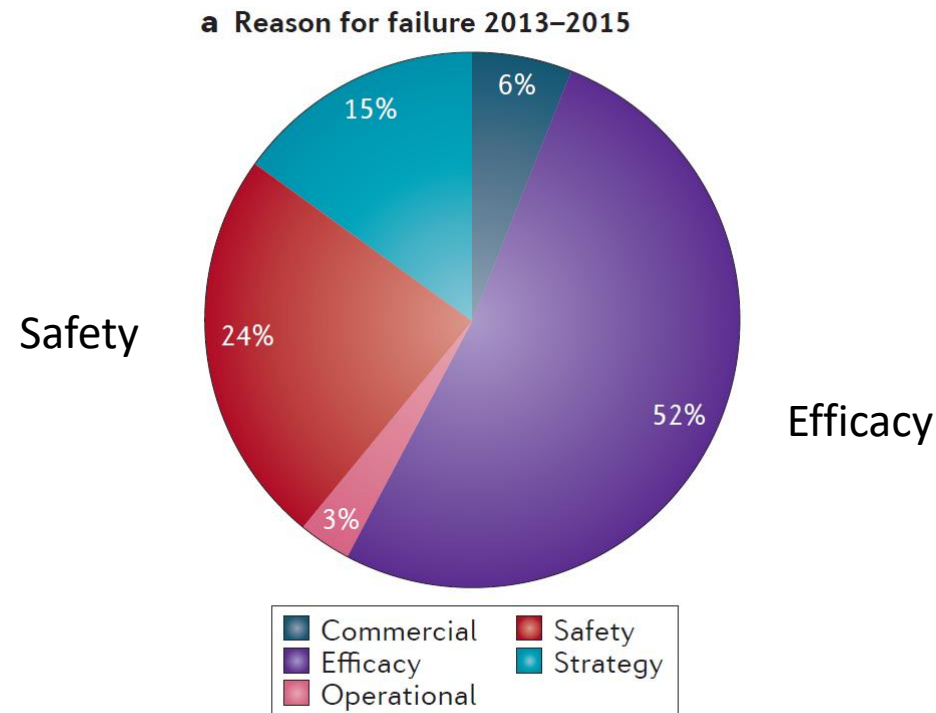
Overall Reasons for Deal Failures



Source: Syneos Health Consulting Dealmakers' Intentions 2018. N=33 for Buyers and N=33 for Sellers.

Where drugs fail

2013-2015 between Ph II (or I/II) and submission



Harrison (2016) Nature Reviews: Drug Discov. 15:817.

How to help your teams

A clear strategy

Enable good decisions on fit

The importance of framing

Introduce diligence with a framework

Can we make this work for us?

All projects have risks – can we solve these?

Tailor the checklists

Make the checklists fit your organizational
structure

Write a
strawman
summary

BD can make a first draft and let team members correct it

Reward diligence team members

BD can't be the regular champion

Reward risk takers who champion

Recognize participation

Celebrate success

Thank you

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