



SR

ADDA Lecture Series: Business Development

UAB

**THE UNIVERSITY OF
ALABAMA AT BIRMINGHAM**

Knowledge that will change your world

“Business Development” Means Different Things to Different Segments of Pharma

- Small biotechnology companies (and the ADDA)
- Big (Branded) Pharma
- Generic Pharma

“Business Development”: A Bit of a Black Box



“Business Development”: Working Definition

- All of our programs are very early in the drug development arc
- We (ADDA) can only take programs to a certain point: IND, maybe Phase I

Business Development:

Finding industry partners that are willing and able to take our programs forward through clinical development and to the market

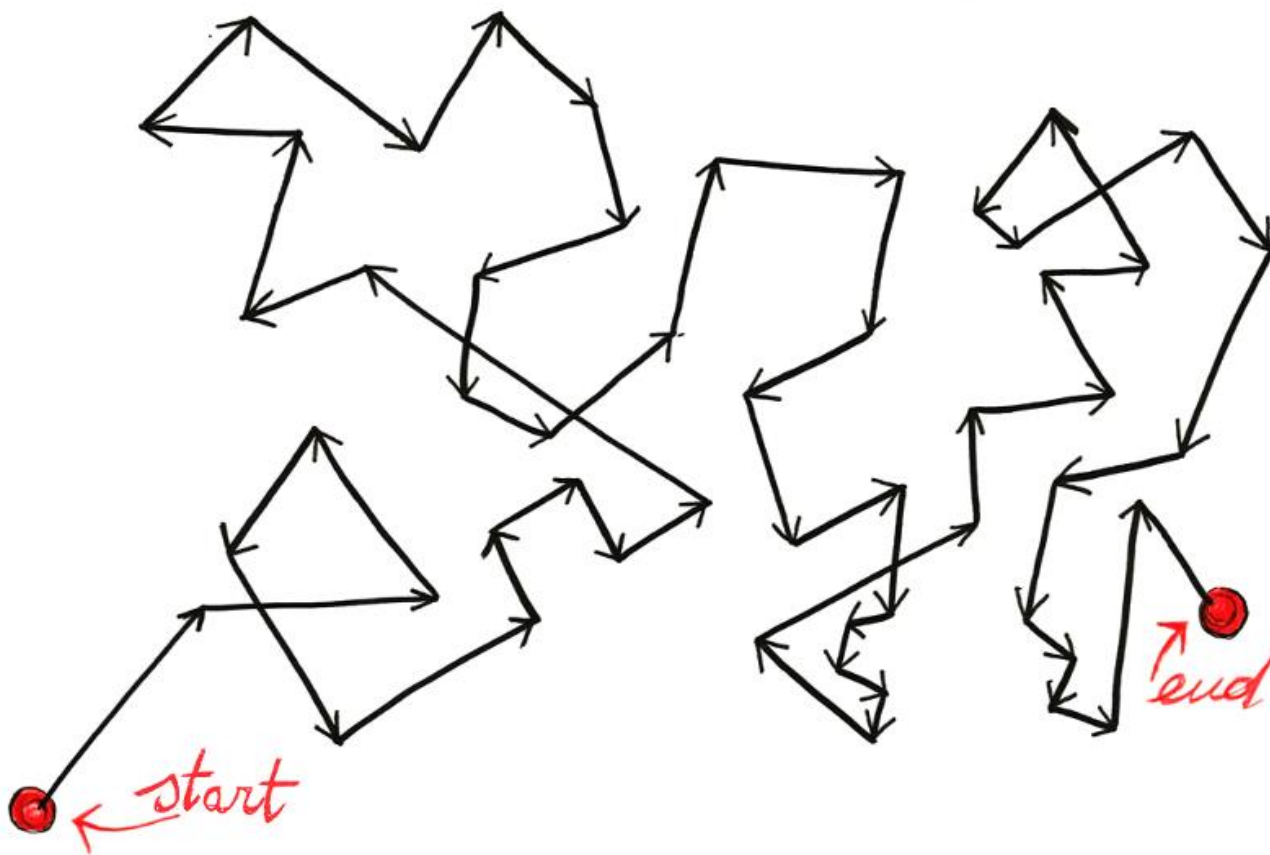
Peeking Inside the Black Box . . .

On paper, licensing a program to a pharma or biotech company is pretty straightforward:



Peeking Inside the Black Box . . .

But in practice, the process looks a bit more like this:



Remember the Fairy Tale . . .

. . . About the princess who goes around kissing frogs to find the one that becomes her Prince Charming?



There's a LOT of that in Business Development

So if you have to kiss frogs . . .

. . . it's important to reduce the “Frog:Prince Ratio” as much as possible!

It is important to understand:

- The potential therapeutic indication
- The competition
- Our program (good and bad)
 - Who is in this therapeutic area?
 - Who has a competing program?
 - Who is open to (very) early-stage assets?
 - Is there any interest in our specific programs?

Reducing the Frog/Prince Ratio

Even with all of the filters applied, we talk with many different types of potential partners

- Big Pharma – includes Big Biotech
- Regional Pharma – EU, JP, KR, etc.
- Specialty Pharma
- Classic Biotechs
- “In Betweeners”
- Investors

And all of the discussions start the same way . . .

“So tell me about your program”



Standard Questions from Companies

- “How far along is the program?”
- “What is your IP status?”
- “Do you have any *in vivo* proof-of-concept?”
- “Is there any clinical or genetic correlation for the mechanism?”
- “How long before you get to IND?”

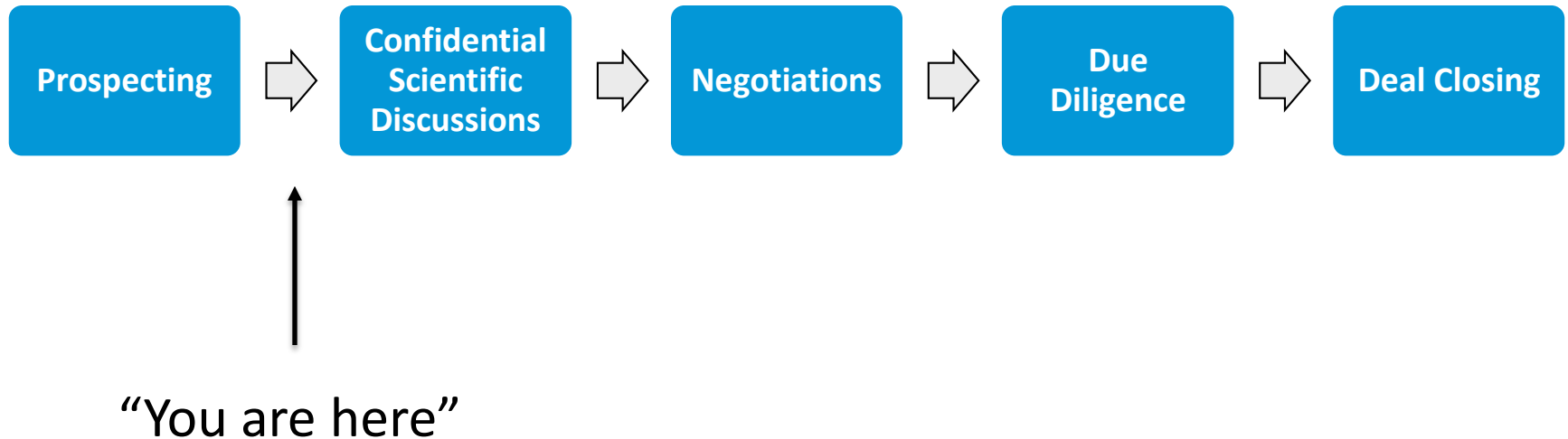
It All Comes Down to the Data

- Without good science, business development has nothing to do
- Basic science
 - Novel insight into disease
 - Clear understanding of mechanism
 - Linkages to clinical samples or genetic studies
 - *In vivo* proof-of-concept
- Applied science
 - Chemistry
 - Pharmacokinetics (including oral bioavailability)
 - Toxicity
 - Intellectual Property

“This program sounds interesting.
I would like to find out more.”



“So the first meeting went well – Now what?”



More Science!

- It is important to get scientific “buy-in” from the potential partner on a program
- If their scientists aren’t excited, or if they have concerns . . .
- Important to have their experts talk to our experts – dive deep into the science

“There is no such thing as too much data.”

Material Transfer Agreement (MTA)

- Often part of the scientific deep dive
- Also referred to as “Trust Yet Verify”
- We provide the potential partner with our compound
- They test it to see if they can reproduce our data
- They might also test it in other systems or models that we don't have

Sounds pretty simple, doesn't it?

Example: Global Pharma

- “The studies are delayed a bit – the technician who does these experiments left the company”
- “OK – we have a new person to do the studies. But the core assay isn’t working . . . We’re not sure why. We’ll get back to you.”
- “Now the studies seem to be working”
- “We decided not to move forward with this program. We couldn’t reproduce your data.”

Example: Chinese Pharma Company

- “We’ve signed the agreement and finalized the studies. But we would like to add one more”
- “Could you send us that one cell line? It would be faster than if we order it ourselves.”
- “Please send us some of that other compound – it would be good to have a positive control. Just in case.”
- “Don’t send anything yet. We just found out that we need to get an import permit from the government . . . We’ll get back to you.”

Coming to Terms

- Term Sheet: A summary of each side's roles and responsibilities in the partnership
- Who pays what and when?
- What is the territory and indication(s)?
- Who makes decisions?
- Who is responsible for
 - Further development steps
 - Patent applications/persecutions
 - Regulatory filings
- What happens if the partner changes their mind?
- How are potential conflicts resolved?

Diligence: Where EVERYTHING is Shared

- Scientific
 - Experiment-by-experiment
 - Notebook-by-notebook
 - Animal-by-animal
- Clinical
 - Dose-by-dose
 - Patient-by-patient
 - All lab values
- Intellectual Property
 - Patents Issued
 - Patent Applications
 - “Freedom To Operate”
- Manufacturing
 - Yields
 - Batch-to-Batch Comparisons
 - Stability

Definitive Agreement

- All agreed-upon terms, wrapped in legalese
- Also includes extensive representations and warranties
 - “Yes, we do have the right to enter into this deal . . . “
 - “We guarantee to use our best efforts . . . “
 - “We won’t sue you if our people mess up . . . “
- Lots of billable hours for the lawyers
- Legal contract, signed by appropriate officers from both sides

Closing the Deal

- Getting final signatures (Hint: Avoid holidays)
- HSR: “Hart – Scott – Rodino”, or “There’s no deal until the government weighs in”
- Cashing the check
- Hitting the bar – hopefully with your new partners!

And then the next morning

- Alliance management
 - “Now that we’re working together, how do we keep track of things?”
 - Meetings, agendas, budgets, reports to senior management, etc.
- Hitting milestones
 - What resources do we have to commit to hit the goals that we committed to?
 - What can we do to help our partner hit their goals?

Deal Timeline

In Theory

- Six months
- Discussions with one or two companies (assuming a good Frog:Prince ratio!)

In Reality

- 18 – 24+ months
- Discussions with up to 40 companies (we hear “No” in many different forms!)

Why Companies Say “Yes”

- They have a gap in their pipeline
- They are invested in the therapeutic area
- A program clearly shows value
 - Scientifically
 - Commercially/Financially
- “Keeping up with the pack”

Why Companies Say “No”

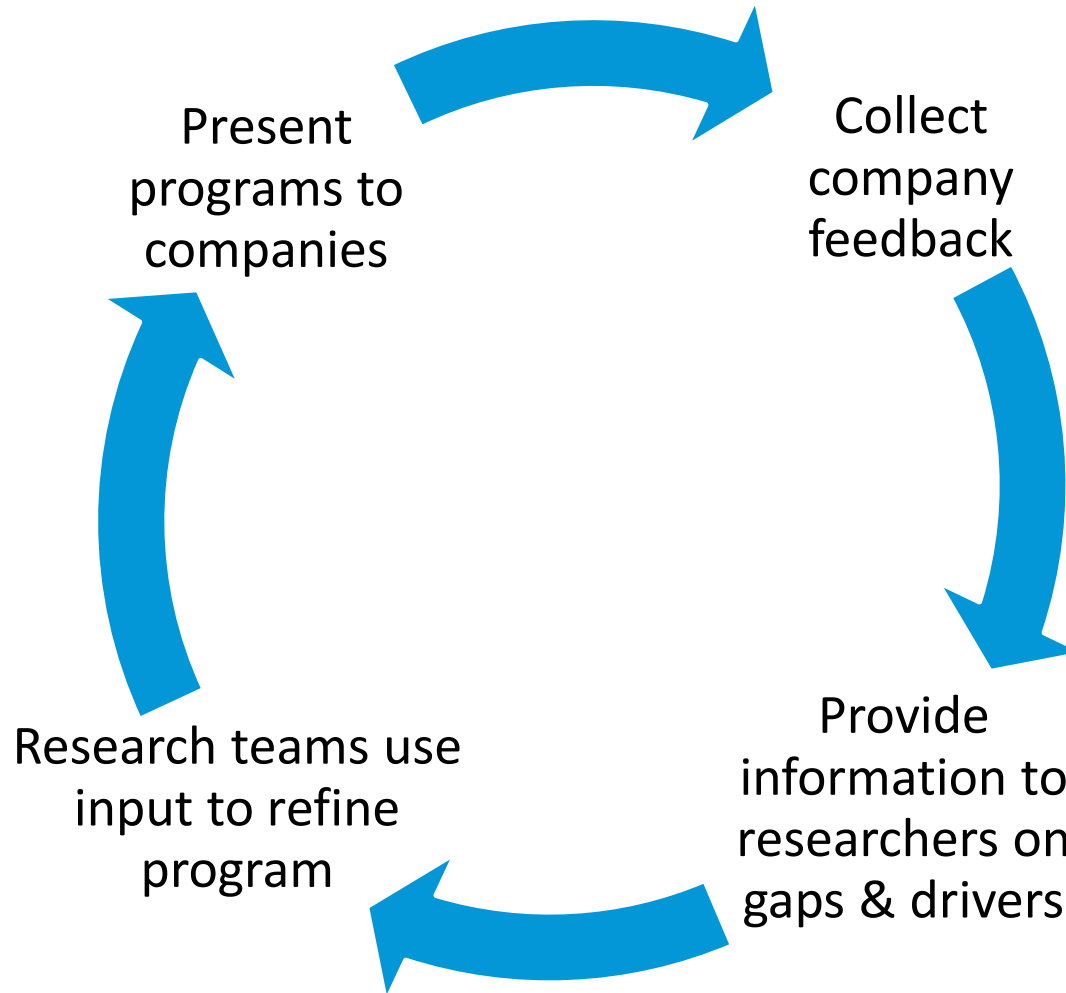
- Program is too early
- They are looking at multiple programs for this indication – and pick another one
- They are simply gathering a little competitive intelligence
- Unresolved scientific questions/concerns
- Financials are too risky or don't add up

Things Change: “Frog” ↔ “Prince”

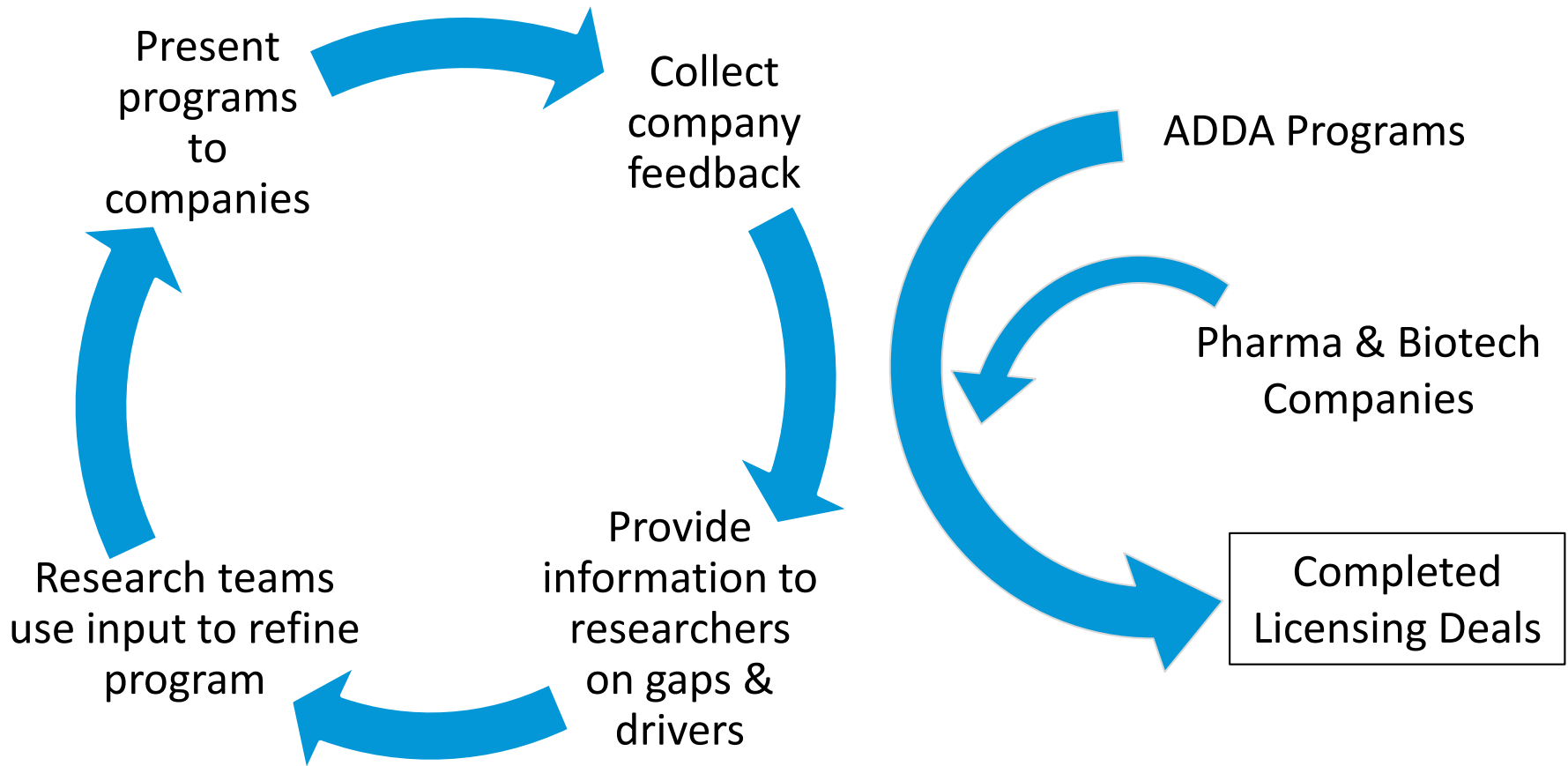
- “There’s been a change in our strategy”
- “We’re getting bought”
- “We need to raise money”
- “The team is being relocated”
- “We’re going through a reorganization”
- “We’re buying someone”
- “Our program failed”
- “We have a new CSO”

Some of these can be good news, some not so good

A Virtuous Cycle



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hardest problems.