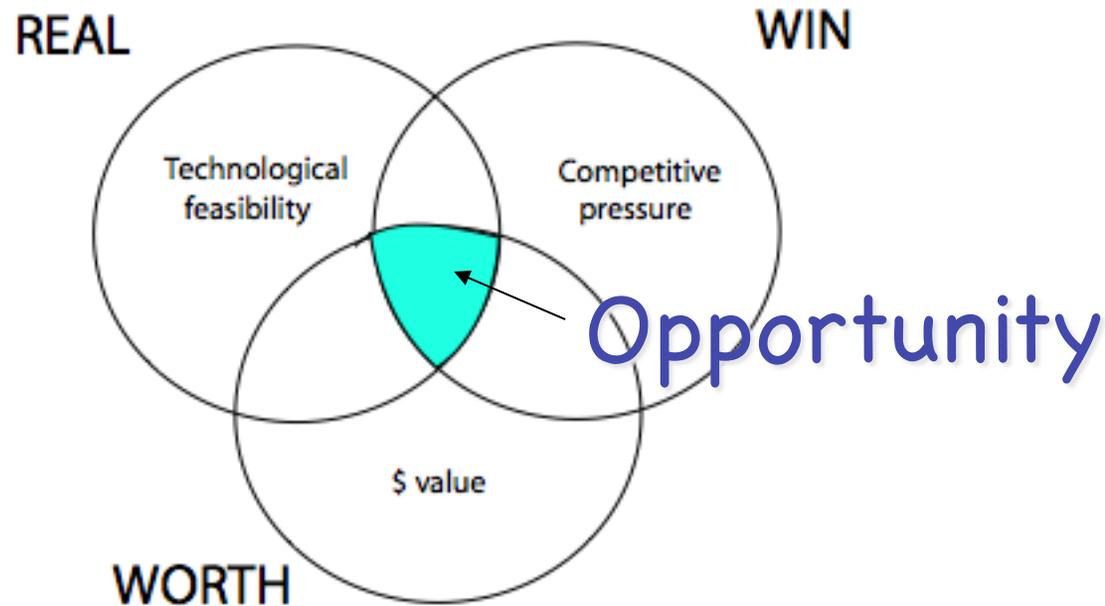


# Translating Complex Biology: Basic Principles That Fuel Successful R&D

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The *quality and efficiency* of your R&D impacts what can be achieved

### The 3 dimensions of strategy



From: Jon Northrup, The Pharmaceutical Sector, in; *The Business of Healthcare Innovation*, Lawton Robert Burns, ed. Cambridge Univ. Press, Cambridge, 2005.

# It connects what you can do with what needs to be done

What can my therapy do?



What needs to happen for  
the patient?



How do they connect?



What is the maximum value  
of that connection?

But while companies large and small aspire to highly productive R&D, these days, too few experience ultimate success from their R&D efforts. Is it luck or...

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Is there a the key element in R&D that can propel your product to the clinic and market?

Is it money?



You don't need lots of money,  
you need *enough* money

And enough money is relative...



Is it time?



You need time but  
time alone doesn't lead to success

Slow for some is  
fast for others  
Guess who wins...



Is it obtaining  
enough information?



The *right* information is vital

Quality, actionable data rules

But the way you use it  
will make the difference!



So what is the biggest factor  
impacting the output from  
preclinical R&D?

Decisions



Deciding

What to do

How to do it

When to do it

Decisions are rarely simple



No matter how the consequences are spun, there will be poor decisions, good decisions and some of the best decisions you'll ever make...



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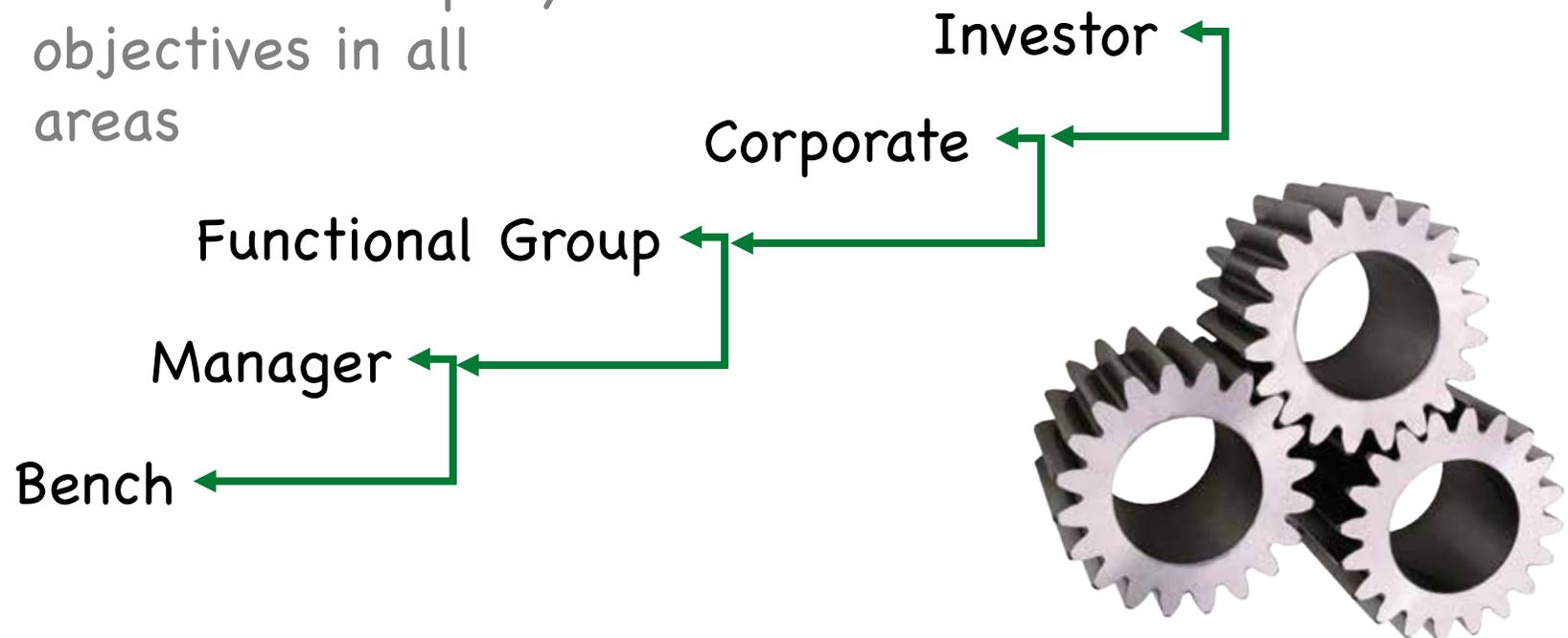
And they directly relate to the level of business risk



# Important decisions are made every day

## At every level of the organization

Objectives should mesh with company objectives in all areas



# Enable good decision-making

“There is a danger that highly skilled professionals will think they are accomplishing something when they are not” Peter Drucker

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In life science, failure to appreciate organizational objectives can cause a development effort to diverge

Be sure to enable genuine decision-making and give genuine responsibility to your staff



Deciding how to tackle  
the challenges

The challenges can't become  
excuses for not succeeding





The fundamental issues have never been a mystery,  
nor will they go away

The questions  
are obvious



“Hold on!  
What’s in there?  
How much do you know about it?  
How will it help me?  
Is it safe?”



Determine whether you are facing a hurdle or a roadblock...



Determine whether you are facing a hurdle or a roadblock...

By appreciating the difference between technical and biological limitations



When is a work around a poor decision?

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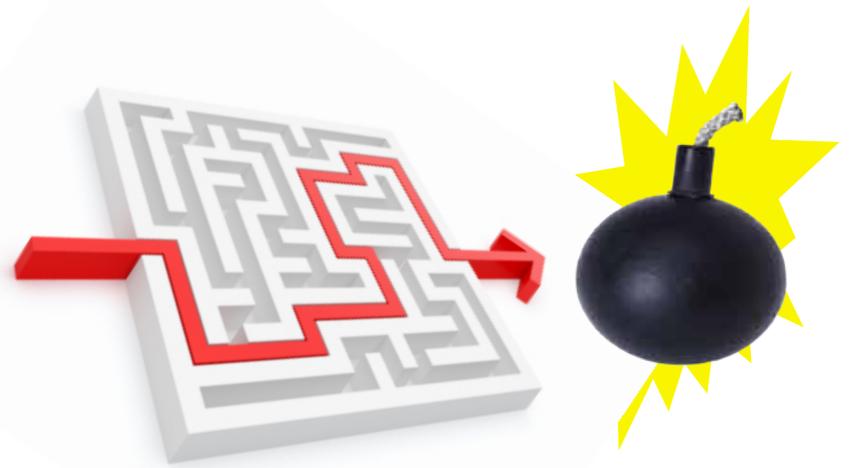
When the result will compromise or otherwise weaken the product from a clinical *or* commercial perspective

# When is a work around a poor decision?

When the result will compromise or otherwise weaken the product from a clinical *or* commercial perspective

When the real reason is to avoid a larger issue

Simply managing  
issues can lead  
somewhere, with  
a lot of time,  
money and effort



But it may not be where you really need to be...

Learn to recognize the times to plug away  
and the times to be fearless

Tackling issues head on in the preclinical phase is what propels you toward success



With less overall time, money and effort

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With less overall time, money and effort

Failing fast is a good thing

When should you invest in innovation to conquer a hurdle?



# When should you invest in innovation to conquer a hurdle?

When it is technical



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When there is reasonable confidence that the innovation will yield a better product



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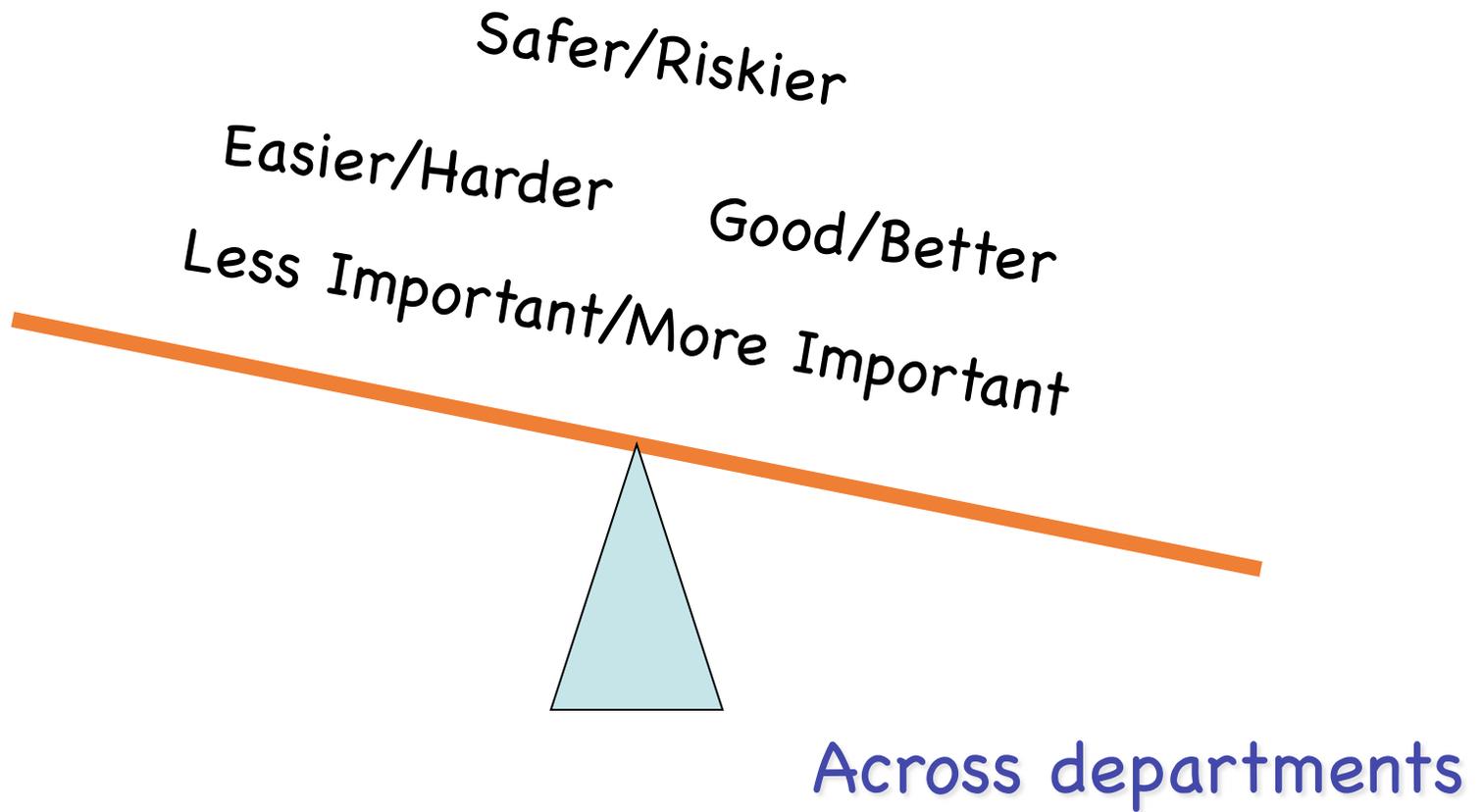
When there is no alternative but to step up!





This requires a **red hot** team with  
High level core competencies  
Innovative thinking  
A balanced, shared perspective  
Clear, meshed objectives  
**CONFIDENCE**

# Balancing what is



# Elements of robust preclinical research...

**Core competence impacts your approach  
to hurdles**

# Core competence will impact your approach to hurdles

Internally you want

A cross- disciplinary team of scientists and engineers

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With a range of both  
knowledge  
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Playing the same symphony



# Core competence will impact your approach to hurdles

## Internally you want

A cross- disciplinary team of scientists and engineers

With a range of both knowledge and technical skills

Playing the same symphony

Supported by experts in key operational areas



The research should be applied, i.e.,  
applicable to your objectives

*Every activity should  
contribute to the advance  
of commercial output in  
some way*



Input has to be managed  
and prioritized to stay ahead...

We can easily drown in external and internal input!



Lack of prioritization needlessly distracts  
sending mixed messages regarding objectives  
impacting the quality of decisions



Don't rely on conclusions in the literature, particularly in the stem cell field...



Use the information and your data to make your own conclusions and strategic decisions

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In industry, you have to get it right the first time

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Use the information and your data to make your own conclusions and strategic decisions

In industry, you have to get it right the first time

Besides, some of the most valuable information can be lurking between the lines...

To prioritize information on an ongoing basis



Maintain focus on the objective

What relationship does the incoming information have to that objective?

Does it lend  
confirmation?

Would it cause you to  
think differently, or do  
something differently?



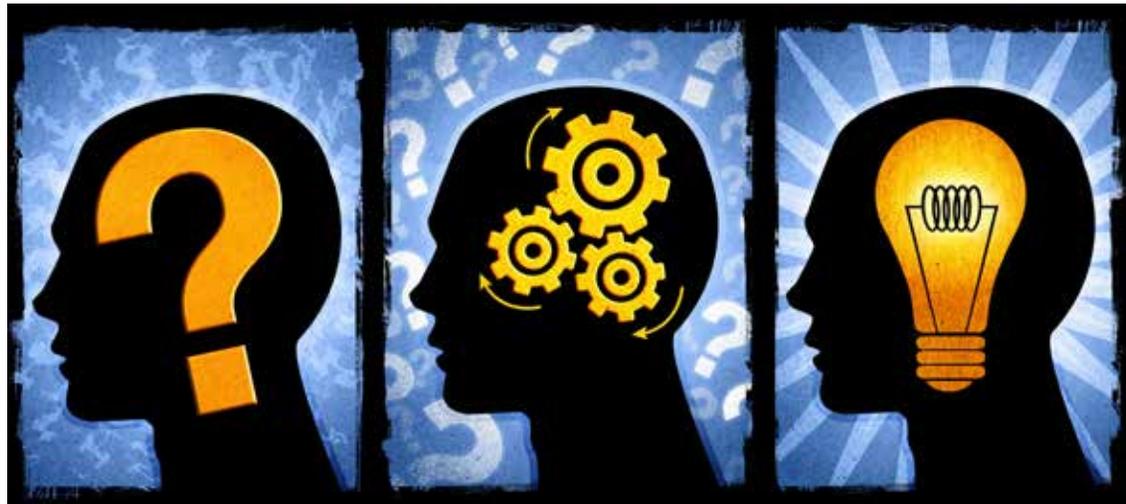
Does it lend  
confirmation?

Would it cause you to  
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something differently?



Then it's valuable knowledge

The goal isn't to know everything,  
but to manage the information so  
that you learn what matters...



Use a similar approach to hone your research activities



Keep the long range objective in sight

What impact will the data have on that objective?

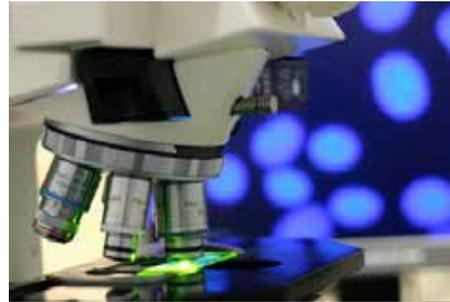
Will the results confirm, enable or cause you to think differently, or do something differently?



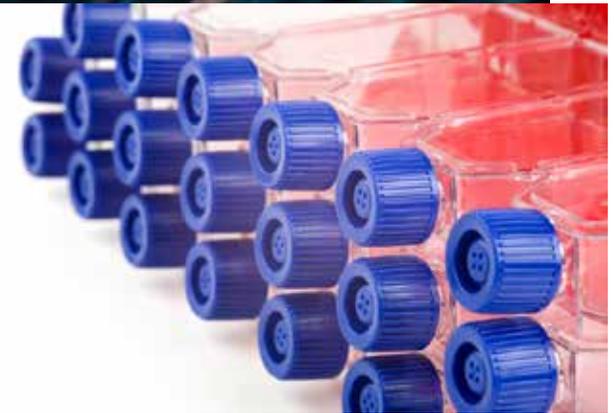
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If not, then why do it?



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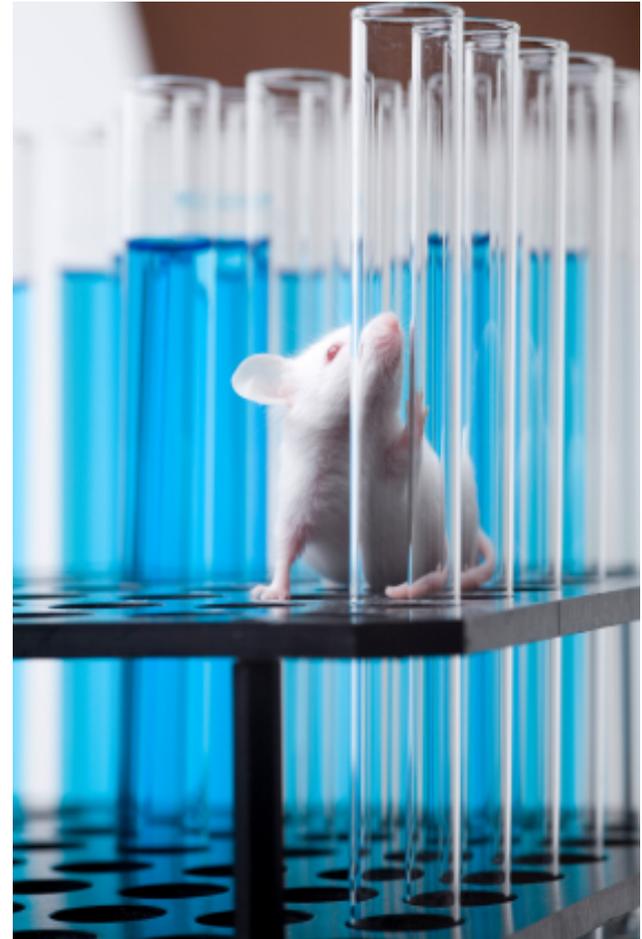


If not, then why do it?

Conduct research based on an applied standard

*In vitro* and *in vivo*  
analyses work best in  
partnership.

Each increases the  
value of the other.



An ideal preclinical plan  
continually

Generates proprietary insight

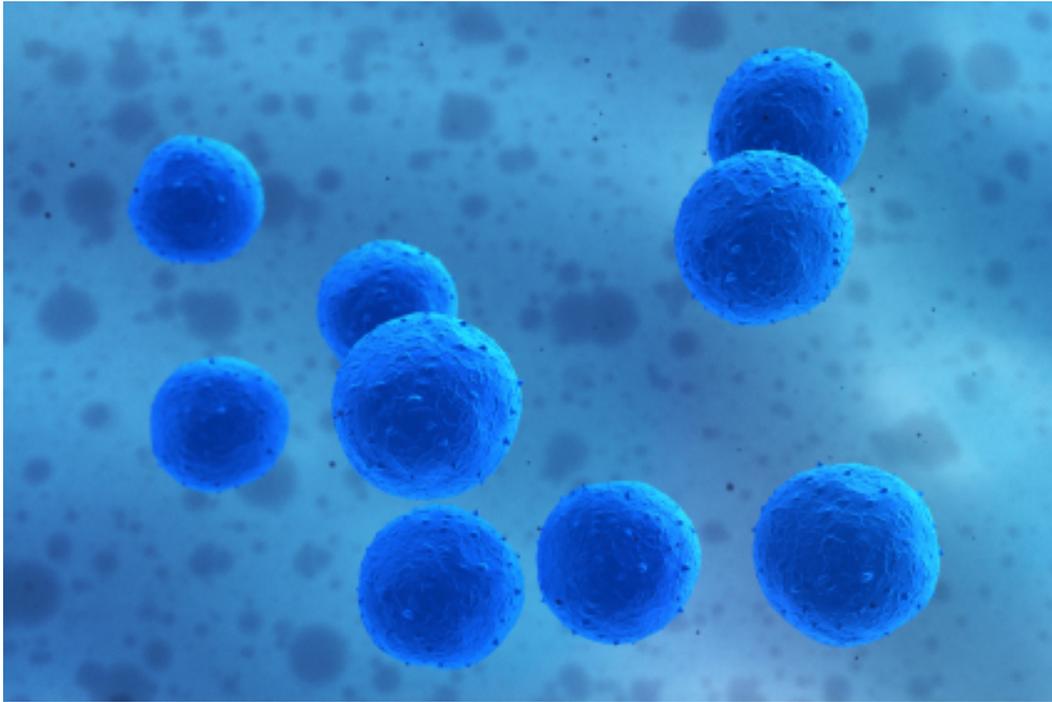
# An ideal preclinical plan continually

Generates proprietary insight  
Creates opportunity

# Ideal preclinical research continually

Generates proprietary insight  
Creates opportunity  
Reduces business risk

A great Preclinical Plan for a biological therapy should...



Determine the “why” and “how”

Connectivity with medical need

Mechanism(s) of action

Generate the information that



Generate the information that

Determines components



# Generate the information that

Determines components  
Defines the product



# Generate the information that

Determines components  
Defines the product  
Sets process parameters



# Generate the information that

Determines components  
Defines the product  
Sets process parameters  
Establishes measures of  
quality and bioequivalence



Be an illuminating  
part of your  
regulatory  
submissions



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Create the foundation for safety

Be an illuminating  
part of your  
regulatory  
submissions



Create the foundation for safety  
Lend scientific support for probable  
efficacy

# Be an illuminating part of your regulatory submissions



Create the foundation for safety  
Lend scientific support for probable  
efficacy  
Assure regulators you know your  
product

Create a preclinical package with ongoing value to the company

Create a preclinical package with ongoing value to the company

That continues to contribute to product acceptance, marketing and physician education to help make the product a commercial success...

A well-managed, properly focused preclinical effort plays a pivotal role in determining what your company can ultimately achieve



Invest in making it the best!

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Parenteau BioConsultants, LLC