

Thinking about Research? How to Identify, Research and Develop

Paul Davis
Trinity Bioactives Ltd
Wellington



Reasons for Research

- i. Traditional knowledge or observation
- ii. Confirm biological activity and possible health benefits
- iii. Seen something related (eg related source)
- iv. Wish to develop new IP position
- v. Make existing product more active (eg new processing)
- vi. Need bioactivity data to complement compositional data
- vii. New potential use of products
- viii. Compare product with competitors
- ix. Understand mechanism of action

Reasons for Research

- i. Traditional knowledge or observation
- ii. Confirm biological activity and possible health benefits
- iii. Seen something related (eg related source)
- iv. Wish to develop new IP position
- v. Make existing product more active (eg new processing)
- vi. Need bioactivity data to complement compositional data
- vii. New potential use of products
- viii. Compare product with competitors
- ix. Understand mechanism of action

Reasons for Research

- i. Traditional knowledge or observation
 - a. Ethnic
 - b. Long standing use (cod liver oil)
 - c. Family (dandelion)

Reasons for Research

- i. Traditional knowledge or observation
- ii. Confirm biological activity and possible health benefits
- iii. Seen something related (eg related source)
- iv. Wish to develop new IP position
- v. Make existing product more active (eg new processing)
- vi. Need bioactivity data to complement compositional data
- vii. New potential use of products
- viii. Compare product with competitors
- ix. Understand mechanism of action

Reasons for Research

Confirm biological activity and possible health benefits

- a. Anecdotal Comments
- b. Long standing use
- c. Evidence to support claims
- d. Benefits for marketing
- e. Regulatory requirements

Reasons for Research

- i. Traditional knowledge or observation
- ii. Confirm biological activity and possible health benefits
- iii. Seen something related (eg related source)
- iv. Wish to develop new IP position
- v. Make existing product more active (eg new processing)
- vi. Need bioactivity data to complement compositional data
- vii. New potential use of products
- viii. Compare product with competitors
- ix. Understand mechanism of action

Reasons for Research

Seen something related

- a. Related species used
- b. Product with many of the same or similar components
- c. Biological relationship (eg collagen effect)

Reasons for Research

- i. Traditional knowledge or observation
- ii. Confirm biological activity and possible health benefits
- iii. Seen something related (eg related source)
- iv. **Wish to develop new IP position**
- v. Make existing product more active (eg new processing)
- vi. Need bioactivity data to complement compositional data
- vii. New potential use of products
- viii. Compare product with competitors
- ix. Understand mechanism of action

Reasons for Research

Wish to develop new IP position

- a. Combination of products
- b. New processing procedure to be protected
- c. New formulation (eg carriers, preservatives)

Reasons for Research

- i. Traditional knowledge or observation
- ii. Confirm biological activity and possible health benefits
- iii. Seen something related (eg related source)
- iv. Wish to develop new IP position
- v. Make existing product more active (eg new processing)
- vi. Need bioactivity data to complement compositional data
- vii. New potential use of products
- viii. Compare product with competitors
- ix. Understand mechanism of action

Reasons for Research

Make existing product more active

- a. New processing
- b. New source of raw material
- c. New time of harvesting
- d. New growing conditions

Reasons for Research

- i. Traditional knowledge or observation
- ii. Confirm biological activity and possible health benefits
- iii. Seen something related (eg related source)
- iv. Wish to develop new IP position
- v. Make existing product more active (eg new processing)
- vi. Need bioactivity data to complement compositional data
- vii. New potential use of products
- viii. Compare product with competitors
- ix. Understand mechanism of action

Reasons for Research

Need bioactivity data to complement compositional data

- a. Competitive advantage
- b. Client requirement
- c. Regulatory requirements

Reasons for Research

- i. Traditional knowledge or observation
- ii. Confirm biological activity and possible health benefits
- iii. Seen something related (eg related source)
- iv. Wish to develop new IP position
- v. Make existing product more active (eg new processing)
- vi. Need bioactivity data to complement compositional data
- vii. New potential use of products
- viii. Compare product with competitors
- ix. Understand mechanism of action

Reasons for Research

New potential use of products

- a. Common mechanism of action
- b. Establish validity
- c. Establish credibility

Reasons for Research

- i. Traditional knowledge or observation
- ii. Confirm biological activity and possible health benefits
- iii. Seen something related (eg related source)
- iv. Wish to develop new IP position
- v. Make existing product more active (eg new processing)
- vi. Need bioactivity data to complement compositional data
- vii. New potential use of products
- viii. Compare product with competitors
- ix. Understand mechanism of action

Reasons for Research

Compare product with competitors

- a. Position in market
- b. Assistance with marketing
- c. Establish specific/unique properties

Reasons for Research

- i. Traditional knowledge or observation
- ii. Confirm biological activity and possible health benefits
- iii. Seen something related (eg related source)
- iv. Wish to develop new IP position
- v. Make existing product more active (eg new processing)
- vi. Need bioactivity data to complement compositional data
- vii. New potential use of products
- viii. Compare product with competitors
- ix. Understand mechanism of action

Reasons for Research

Understand mechanism of action

- a. Multiple pathways possible
- b. Helps establish validity
- c. Professional acceptance
- d. Peer-reviewed publications
- e. Marketing advantage

Reasons for Research

So, need to do some research

Chemical composition

Biological activity assessment

So, where to start?

How to go about it?

Reasons for Research

How to go about it?

No one track to give yes/no

Multiple possibilities

Reasons for Research

What is the biological activity to be measured?

Needs thought,
discussion
consideration

Then, what is the most appropriate way to go about it?

Reasons for Research

- Cost of research
- Frequently start with laboratory based investigation
- Needs to be appropriate methodology

Reasons for Research

Biological activity

- Laboratory based
 - Cell culture
 - Tissue culture
 - Biochemical (eg enzyme)
 - Immunological
 - Molecular biological

What is the most appropriate (fit for purpose)?

Reasons for Research

- Multiple samples (screening process)
- Appropriate protocol - can provide indication of biological activity
 - some indication of mechanism of action

Reasons for Research

Several different laboratory investigations

- Further characterise bioactivities (multiple?)
- Further characterise mode of action (multiple pathways?)
- Fuller knowledge about biological activity

Reasons for Research

Product biologically active

So what?

Lab based results

Doesn't mean that it works and has same activity *in vivo*

Reasons for Research

Reasons for *in vivo* investigation if possible

- a. Whole animal – (complicated physiological, biochemical and maybe pathological factors)
- b. Appropriate form of administration
- c. Indications of toxicity, adverse reactions
- d. May have animal as well as human health applications

Not always possible

- a. Appropriate model not available
- b. Animal Ethics Committee approval

Reasons for Research

Animal Study

Designing study

- No. of animals in group (Statistics)
- Appropriate model
- Control groups
- Ethics approval
- Appropriate administration (eg oral)
- Maximum amount of information

Reasons for Research

Animal Studies

May require more than one investigation

- a. Efficacy
- b. Optimal dose
- c. Preventive vs therapeutic
- d. Safety, Adverse effects

Reasons for Research

Animal Study

Outcome and Consequences

- Administration to live animals works/doesn't work
- Human Ethics Committee application

Reasons for Research

Translate to Human response

YES / NO

- Example: Endostatin in mice

Reasons for Research

Costs of Research

- Funding assistance
- Several sources
- Any size of project eligible

Reasons for Research

Dr Paul Davis
Trinity Bioactives Ltd
P O Box 15-135
Miramar
Wellington

Tel: 04 974 9286
021 424 622
Email: p.davis@trinitybioactives.com
Web: www.trinitybioactives.com