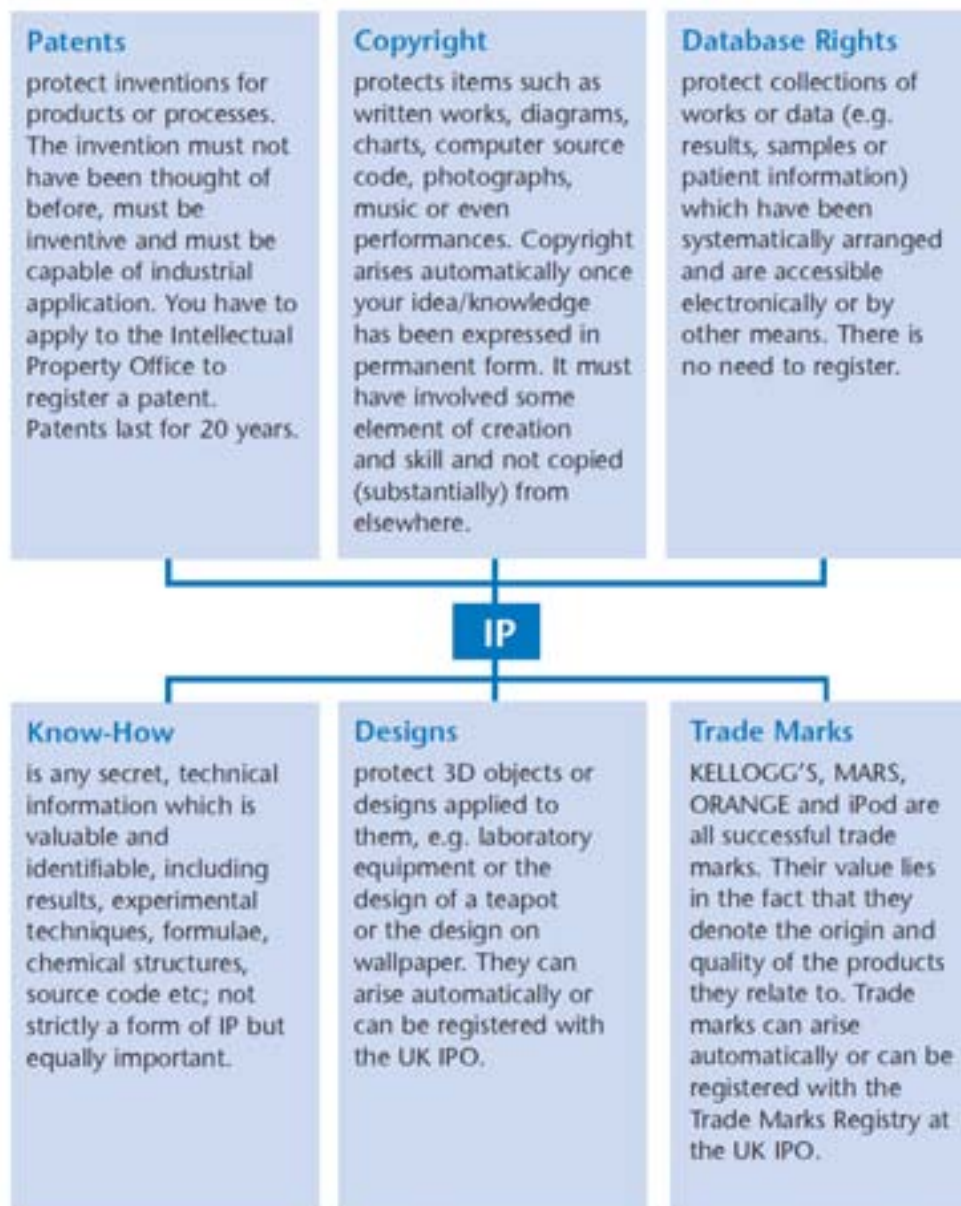


# Intellectual property exploitation and the successful translation of research

***Jeremy Pearson***



- Defining and protecting Intellectual Property
- Deciding on the best way forward
- Apparent barriers – the BHF perspective
- Funding routes



Once a patent has been granted, it offers the owner a 'monopoly' right. This means that only the owner, or someone else with the owner's consent, can use the invention for commercial purposes. Say you have thought of an invention for a new type of tea bag which can be used 50 times without losing any flavour! Useful. This invention will be patentable if: (1) it has not been disclosed publicly anywhere in the world prior to filing the patent application; (2) it is inventive; and (3) it is capable of industrial application, (essentially any commercial, medical or other practical use).

If you think your invention is potentially patentable it is essential that the details of the invention are kept secret until the application for the patent is made. Disclosure of the key features of the invention before that will make your patent application invalid and so may be refused or be open to challenge in the future if granted.

Methods of disclosure may include publishing details of the invention:

- in a journal, book, poster or other publication
- via a website other electronic means
- in an oral presentation
- to someone who is not an employee of your organisation, such as a student, or is not bound by confidentiality to keep such information secret.



**Q: How do I know if my invention is already in the public domain?**

**A:** A previous disclosure can include anything from a published patent, document, information contained in a book, article, journal, TV documentary, demonstration or even just common practice. Whilst you cannot expect to find everything, a good starting point is to see if there are any existing patents which relate to your invention. It is easier than ever to find patent information as the format of patents has become increasingly standardised and there are many user-friendly websites that you can search.

If you are not experienced in patent searching you can obtain advice and assistance from the range of Patent Libraries located throughout the United Kingdom. There is also a wealth of information on-line. Both the UK Intellectual Property Office and the US Patent and Trade Mark Office have on-line services ([www.ipo.gov.uk](http://www.ipo.gov.uk) and [www.uspto.gov](http://www.uspto.gov)). You can also connect directly to [esp@cenet](mailto:esp@cenet) which gives access to details of many patents worldwide (<http://gb.espacenet.com>).

Alternatively there are firms and consultants based throughout the UK which specialise in patent searching and related services. Most firms of Patent Agents will offer 30-60 minutes of consultation free of charge. If you think you need this help, contact your IP commercialisation organisation for further help.

| Practical tips  |  |
|---|--|
|    | If you come up with a new invention, is it patentable (see Section 1)? Consider whether your invention has been previously disclosed – e.g. look at existing patents, key word searches. Use the internet, in particular esp@cenet.  |
|    | <p>Keep both originals and copies of all notes, reports, drawings, lab books etc. relating to the invention in a secure place. You should try to record as much detail as possible. Ensure all originals and copies are dated and are sufficiently detailed (and clear!) to identify the invention and how it works. Get your supervisor to sign and date laboratory notebooks on a regular basis.</p> <p>Keep the invention confidential (see Section 4 for practical tips on confidentiality). If you need to disclose any information, you should first speak to your supervisor.</p> |
|    | If, having done your initial searches/investigations you still think your idea is patentable, let your supervisor know and contact your IP commercialisation organisation to set up a meeting.   |
|  | If it is decided to go ahead, a patent application can be drawn up, usually with the help of a patent agent, and filed at the UK IPO. Once filed, you can indicate on any relevant marketing literature, publications or products "Patent applied for, No. [NUMBER]". Do not do this before you have filed, as it is illegal to do so.   |

## Can I present at a conference?

If you disclose the key information about your invention or design whether at a conference or elsewhere, it can stop you getting IP protection. You may, however, be able to make some general statements without disclosing your invention. Discuss this in advance with your IP commercialisation organisation.

If you disclose your design, you will have 12 months to file the application. Speak to your IP commercialisation organisation immediately.

If you disclose your invention, you may still be able to get patent protection in the USA if you file the application within 12 months, but anyone will be able to use your invention almost everywhere else in the world.

So if you are about to publish at a conference or elsewhere, speak to your IP commercialisation organisation as early as possible. They will look to file an application for a patent before publication, if the subject material has good business prospects.

You can publish openly once a patent application has been filed. There can be some advantage in waiting a little longer before publishing, in case any claims of your patent are not accepted by the Intellectual Property Office. These rejected aspects of your application can then only ever be protected by confidentiality.



## What should I do to protect the information?

You may have heard references made to a 'CDA' or 'NDA'. These are abbreviations for "Confidential Disclosure Agreement" or "Non-Disclosure Agreement". If you have to disclose important information always try and put a written agreement of confidentiality in place. The best thing to do is contact your Research Office or IP commercialisation organisation or your supervisor who will no doubt have a sample confidentiality agreement for you to use and will be able to help with putting it in place. Remember you are probably not authorised to sign a confidentiality agreement for your institution.

These agreements are all to be taken very seriously. Any information and discussion covered by them must be treated in confidence and not disclosed to anyone else, except as set out in the agreement. If there is any breach of any agreement, the other party may be entitled to seek financial and other compensation (damages) not only from your employer but possibly from you personally. This is obviously a very serious matter. In an environment like a university or NHS Trust it is difficult to supervise closely compliance with all the agreements that have been signed. There is also, of course, a natural desire to publish and discuss work openly, which may on occasions give rise to individuals not realising the importance or the extent of any agreements that have already been signed. Extra care therefore needs to be taken.

**Q: I was recently provided with a number of tissue samples from an outside company for my project. I also received a document referred to as an 'MTA' with the samples. What should I do?**

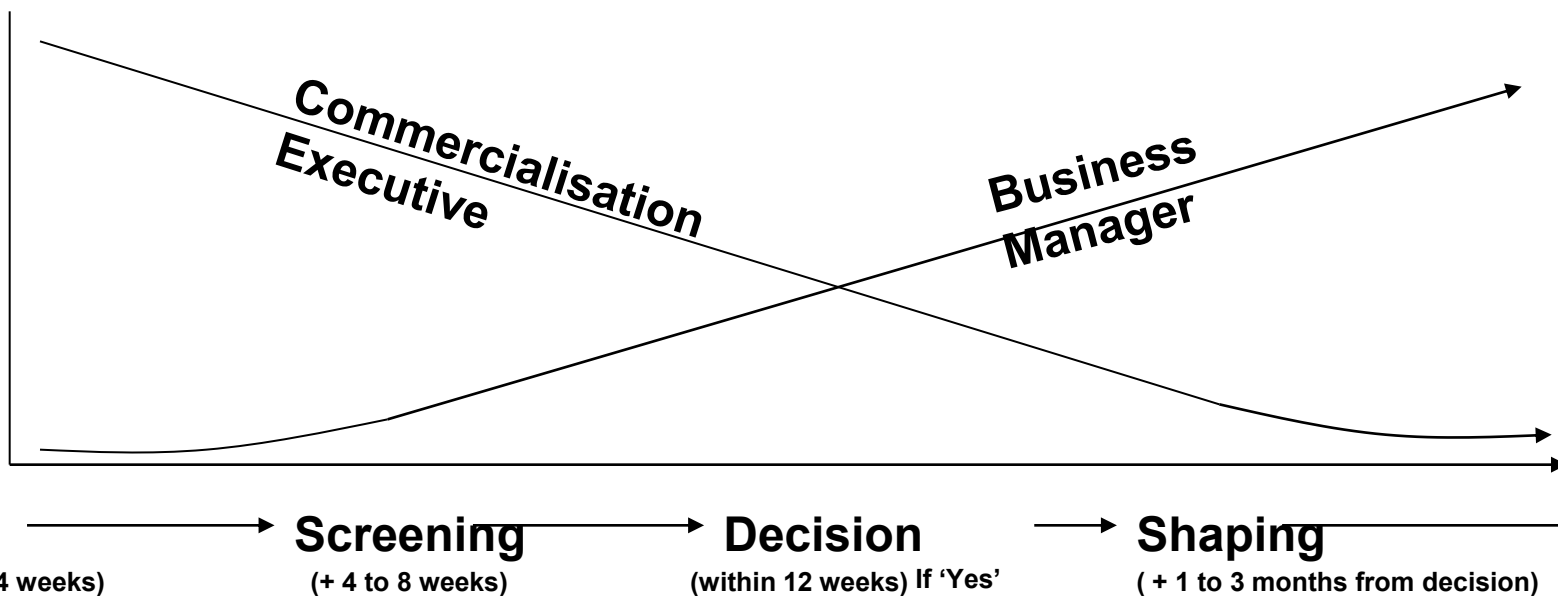
**A:** MTAs are Materials Transfer Agreements. This agreement is likely to contain a number of restrictions on what you can and cannot do with the samples, how you must deal with the results and whether, for example, you must return any back to the company. It is important to read through the terms carefully and speak to your supervisor and/or your IP commercialisation organisation. They will let you know whether it is appropriate and who is authorised to sign it. You must remember that when any kind of materials are provided to you it is possible they may contain confidential information or they may even be protected by a patent. By using materials which are protected by a patent in a manner which the owner has not permitted you may risk infringement. Some MTAs may even try to take ownership of IP created by you.

- Defining and protecting Intellectual Property
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# A judgemental process

- Its not an exact science
- Seeks quantitative and qualitative data
- Relies on experience
- The process asks key questions





|                   | Phase One  | Phase Two  | Phase Three   | Phase Four  |
|-------------------|--|--|---|---|
| <b>Activities</b> | <p>Meet Academic(s)</p> <p>Information Gathering on:</p> <ul style="list-style-type: none"> <li>- Technology or Idea</li> <li>- Possible Applications</li> <li>- Stage of Development</li> <li>- Industry Links</li> <li>- IP Position</li> <li>- Research Funding</li> <li>- Academic Background</li> <li>- Publications</li> </ul> | <p>Search for Prior Art</p> <p>Assess Strength of IP</p> <p>[Arrange Independent Technical Assessment]</p> <p>Identify Products or Services</p> <p>Identify Customer(s)</p> <p>Validate Market Applications</p> <p>Conduct Market Analysis</p> <p>Define Benefit/Added Value</p> <p>Research Competitors</p> <p>Test Academic Commitment</p> | <p>Review</p> <p>Outcomes:</p> <p>EITHER: Reject, then</p> <p>Inform Academic(s)</p> <p>Signpost Elsewhere</p> <p>OR: Accept, then</p> <p>Allocate resource</p> | <p>Protect IP</p> <p>Define Commercial Plan</p> <p>Seek Funding (if required)</p> <p>Confirm IP Assignment</p> <p>Formalise Arrangements with Academic(s)</p> <p>Determine Milestones</p> |

# Stages of assessment

- **Invention disclosure meeting: initial assessment**

**Market, People, Technology, IP ownership**

- **Deeper assessment**

**Market size, market need, USP,**

**Market route, Technology confidence,**

**barriers, competitors, finance**

# General rule

- It generally takes much **more** effort to commercialise a technology that only has a **modest** set of ingredients than it does for one that has a **strong** set of ingredients
  - Risks higher
  - Fund raising more difficult
  - Time to market longer
  - Returns smaller

# Overall market size

- **Information gathering**

- What is the full range of applications that the technology could be used for?
- Market reports
- Data on existing companies e.g. turnover
- Market validation
  - Contact end users, distributors, industry insiders



# Unique selling proposition (USP)

- What are the features of the technology that would make it the technology of choice
  - Function
  - Cost
  - Quality
- How novel/attractive would it appear to a user/customer?
- Is there a clear unmet need?
- **Information gathering**
  - A thorough knowledge of the existing and emerging technologies
  - Dialogue with end users/distributors/industry insiders

# Route to market viability

- Is there a credible route to market?
  - Existing distributor chains/outlets?
  - If no, does setting up an appropriate route to market seem
    - Sensible/affordable
  
- Information gathering
  - Typical margins and overheads in existing distribution systems
  - Identify key players - assess what would motivate them to work with us
    - make contact if appropriate

# Confidence in the technology

- Do we have clear proof of concept?
  - Function
  - Scale up potential
- Clear understanding of the technical risks/downsides/limitations
- **Information gathering**
  - Potential external technical critique, testing or evaluation
  - A good understanding of the investment required to bring to the technology production.

# Barriers to competition

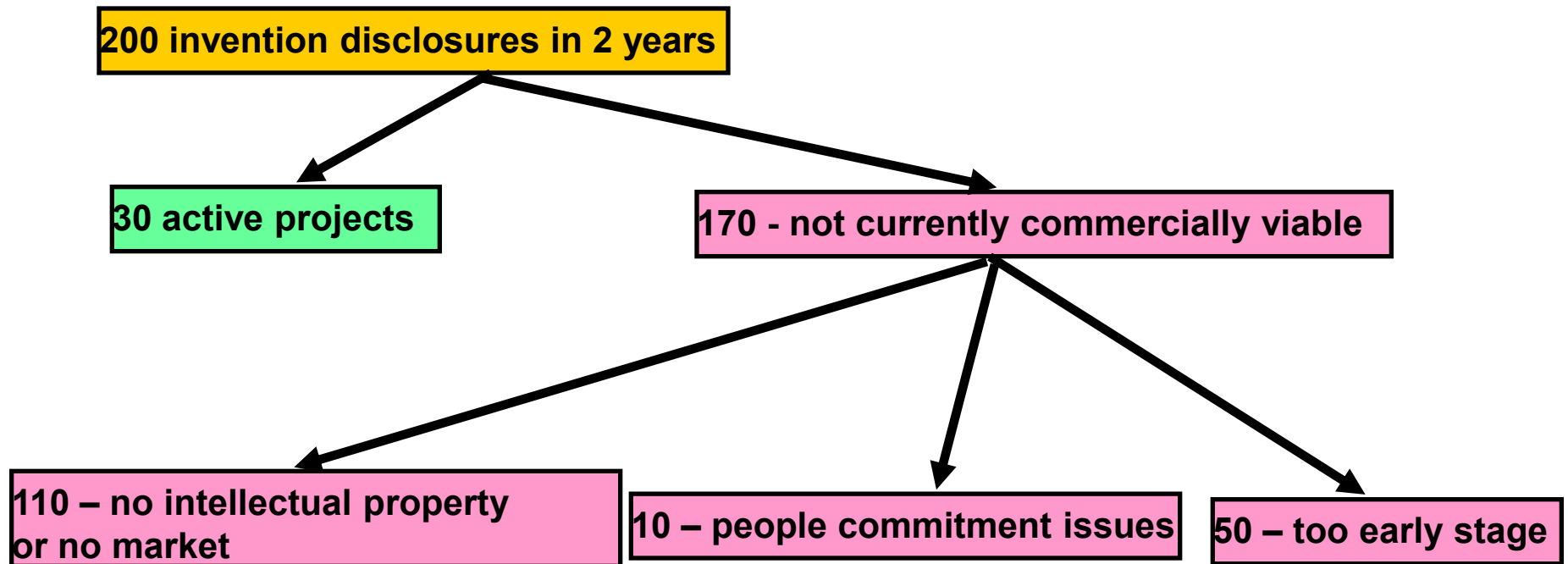
- Does a strong intellectual property position exist currently?
  - Patents
  - Know how
  - Software
- If “no”, is there a good likelihood that strong IP will be developed from the work ahead?
- If “no” to both of the above
  - Are there any other measures that could be taken to help the technology/product stay ahead of the competition
    - Customer benefits
    - Cost
- **Information gathering**
  - Prior art searches of existing and potential future IP
  - Identify Specific skills and expertise that are not replicated elsewhere
  - Technology road map
  - Can it be kept secret?



# Market dynamics

- Do the dynamics for this market match the timing of the product/technology?
  - A new mobile phone technology may be very risky if it has a 5 year development plan
- What are the market trends/pace/volatilities?
- **Information gathering**
  - Project timing plan
  - Legal or regulatory requirements/constraints

# Experience at Manchester - EPS data



- Defining and protecting Intellectual Property
- Deciding on the best way forward
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# The BHF's experience

- Employed a Research Translation Consultant, Dr Anna Obolensky, to survey our grants



# Understanding the past

- For the past 50 years the BHF has spent incrementally up to £100 million per annum on basic and clinical research in cardiovascular disease across 43 UK universities with over 1000 grant awards to more than 500 principal investigators.
- However, during this period there have been very few revenues to the BHF from funded research.

**Why?**



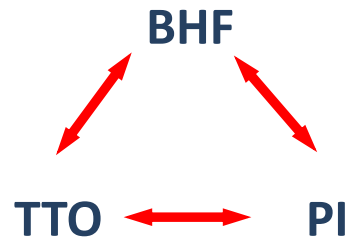
# Problems in identifying IP

- What are the existing difficulties in searching for IP?
- The **Technology Transfer Office** (TTO) is wary of 'outsiders' effectively doing its job i.e. identifying and exploiting IP within its own university.
- The **PI** may feel uncomfortable – and that they are being 'checked-up on'.
- Finding IP is **facilitated** where the PI is funded by the charity and particularly if the T&Cs of any award specify a revenue share from commercialisation.
- Finding IP in universities is critically dependent on a **good working relationship** with the university TTO.



# Clarifying the BHF's role

- Very clear understanding is needed from the outset that the objective of the charity is to enhance treatment options available to patients and to progress research from the university into the clinic.
- In other words there needs to be a diplomatic exercise resulting in a close relationship between:



- The TTO stands to benefit from the special expertise of the charity and its sector specific industrial contacts.
- The charity can harness the commercialisation expertise of the TTO.



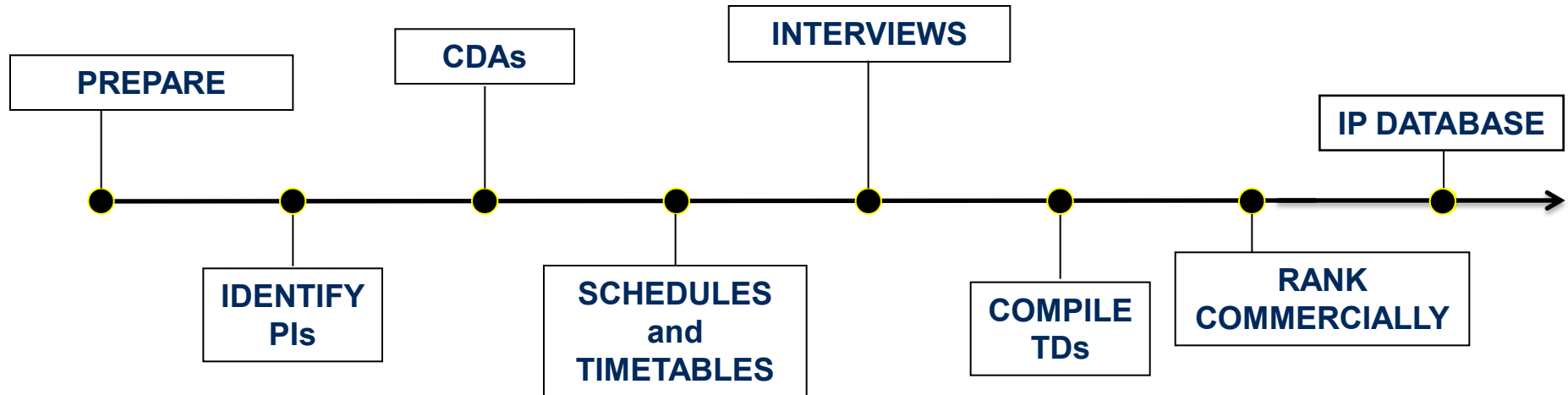


# Groundwork

- When looking for commercially important IP within university it is important to understand what you are looking for and why.
- The ground work must include good understanding of :
  - **Unmet clinical needs of the disease**
  - **Key research methods and technologies**
  - **Strategic focus of business development in industry**  
For a medicinal product this will include therapeutics, diagnostics, imaging, medical devices and regenerative medicine companies.
- It is **critically important** to prepare questions specifically related to IP or you will get the wrong answers - many PIs do not know what it is.



# Building a portfolio





# First survey 2010

- BHF Commissioned an audit to look for IP with potential for clinical translation across the 4 BHF Centres of Research Excellence.
- The study also interrogated some of the reasons why potential IP was lying dormant within the university research base.
- A systematic planned and informed approach was implemented over 6 months.
- One month was spent in preparation, 4 months doing interviews in the field, and one month compiling the TDs and the report



# The process

1. Confidentiality agreements (**CDAs**) were put in place between the BHF, the four universities (Oxford, Edinburgh, Imperial and KCL) and the consultant.
2. About 20 **PIs were selected for interview** at each CRE according to recommendations from Senior BHF scientists at the host university, the TTO and the BHF medical Research Team.
3. Face to face **structured interviews** were then carried out over 4 months.
4. One page **technology disclosures (TDs)** were drawn up for each research project.
5. Each technology was then allocated an **IP code** (Tx, Dx, etc.) and a subcategory (e.g. atherosclerosis, stroke, heart failure).
6. Each technology was **commercially ranked** according to nearness to translation.



# Structured interviews

## **The Technology Disclosure Fact Sheet**

- The research group and the university/institution
- The technology itself - key differentiator/unique aspect of the research
- Why the technology may be translational or of clinical importance
- The IP status of the technology
- The engagement with industry/funding bodies to date
- The status of the technology – ongoing, milestones, roadblocks?
- The associated literature
- The commercial ranking in the light of these points (traffic light system)



# Results

- 60 TDs were commercially and technologically ranked (10 of which were previously unknown to the TTO).
- 41 TDs were of potential commercial interest and non-confidential disclosures signed off by the TTOs were forwarded to industry, leading to 5 expressions of direct interest from potential commercial partners.
- 6 new patent applications were made.
- This study clearly demonstrated that within the four BHF Centres of Research potential IP was :
  - Not being identified
  - Not being patented
  - Not being protected
- Where there is no clear ownership of the IP endorsed by patents, translation of this research becomes significantly more difficult.





# Problems identified

## **PIs**

- Often do not know what IP is.
- Not sure when or how to apply for patents.
- Not aware that publication (abstracts for meetings/papers) or presentation of research puts IP in the public domain.

## **TTOs**

- Lack sufficient internal resources.
- Driven by research outputs not market forces or clinical need .
- Lack sector specific expertise/good commercial contacts in the CVS arena.

## **BHF**

- More education for PIs on the importance of IP on award.
- IP needs to be mentored more closely.
- More translational funding awards.



# Second audit 2011-12

- Over 12 months using the systematic approach described, 9 universities were audited for IP generated by BHF funded PIs.

## In total

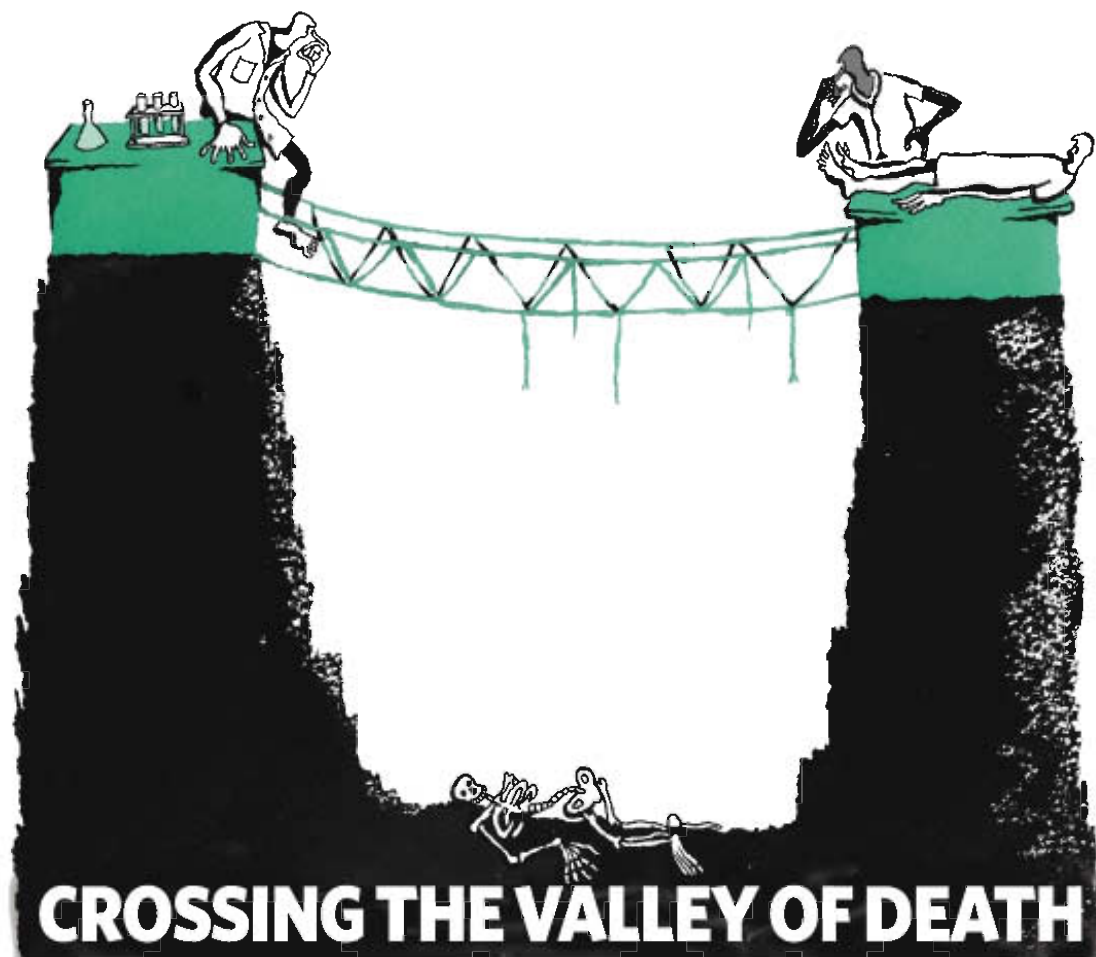
- **176** PIs were contacted and 146 agreed to interviews.
- **163** TDs were drawn up as one-page fact sheets and ranked commercially according to nearness to translation. Of these 33 were new to the TTO.
- **22** new patent applications were made.
- Of the ranked technologies 48 were 'green' and were re-evaluated in the light of the range of technologies now accounted for.
- **15** of these are currently being further evaluated with a view to translation.



# Conclusions

- The BHF now has a much clearer idea of the potential commercial value of the research it funds.
- It also now has an internal database which logs the research according to IP, which can then be tracked as it reaches (or fails to reach) commercial milestones.
- Industry seeking research can approach the BHF directly and partnerships can be forged earlier and more easily bringing more research to the clinic.

- Defining and protecting Intellectual Property
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## The Need for a New Approach in Developing New Therapies



- Academic research doesn't take discoveries to an 'investable' point
- Traditional granting sources and angel funds are not sufficient to fuel the growth of the life sciences industry given the lack of venture funds
- Gap exists between discovery and translation into commercial opportunity





## Translation Fund

Translating ambitious, applied R&D projects with an unmet healthcare need.



## Innovative Engineering for Health

Funding for biomedical engineering research and development to address major challenges in health.



## Seeding Drug Discovery

Facilitating early-stage small-molecule drug discovery.



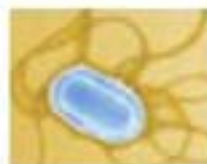
## Health Innovation Challenge Fund

Themed calls for innovative healthcare technologies delivering near-term patient benefit.



## Affordable Healthcare in India

A Wellcome Trust scheme to support R&D in India to develop accessible healthcare solutions



## Pathfinder Awards

Academic-Industry funding to develop early-stage applied R&D in orphan and neglected disease areas.



The screenshot shows a web browser window displaying the MRC Technology website. The browser's address bar shows the URL <http://www.mrc technology.org/>. The website's header includes the MRC Technology logo, navigation links (Home, About Us, Vacancies, Sitemap, Contact Us), a phone number (+44 (0)20 7391 2700), and a search bar. The main content area features a large banner with the text "INTELLECTUAL PROPERTY COMMERCIALISATION & MANAGEMENT for your organisation's life science research". Below this, it states "We help academic, charity and not-for-profit organisations that need assistance with:" followed by a list of services: "Identification, protection, management and partnering of life science intellectual property", "Development of drug and antibody targets", and "Management of pre-clinical funding programmes". To the right of the banner, there are two columns of links. The "Tech Transfer" column includes links for "Intellectual property management", "Commercial development", and "Business development". The "Industry" column includes links for "View our knowledge opportunities", "Find out about our antibody commercialisation service", "Work with us on early stage drug discovery programmes", "Regeneration advice", and "Contact us". The browser's taskbar at the bottom shows various application icons and the system clock indicating 11:23 on 15/06/2013.

**INTELLECTUAL PROPERTY COMMERCIALISATION & MANAGEMENT**  
for your organisation's life science research

We help academic, charity and not-for-profit organisations that need assistance with:

- Identification, protection, management and partnering of life science intellectual property
- Development of drug and antibody targets
- Management of pre-clinical funding programmes

**Tech Transfer**

- ← Intellectual property management
- Commercial development
- Business development

**Industry**

- View our knowledge opportunities
- Find out about our antibody commercialisation service
- Work with us on early stage drug discovery programmes
- Regeneration advice
- Contact us



## About our Development Gap Fund

The Development Gap Fund is a pre-seed translational research fund. It offers funding, in the form of staff and consumable costs, to scientists from MRC Units and Institutes to conduct translational research with commercial potential in their laboratory and/or in collaboration with our Centre for Therapeutics Discovery.

The fund was first launched in 2003, with funding of £4.5 million, and was extended in 2008 with a further £6 million.

More than 65 projects have been funded so far. Our successes include:

- Formation of [Heptares Therapeutics Ltd](#), a GPCR drug discovery company, which raised a Series A fund of £21m in February 2009
- Development of a simple sponge device for the detection of oesophageal cancer
- A [modular website](#) offering validated and supported tests for the assessment of cognitive function

## What we look for

We would like to hear about commercially interesting ideas/projects where clear value can be added. This might include proof of concept studies, target validation components of drug discovery, assay development and device/diagnostic prototyping.

Typical awards are £20-200k over two years, for salaries and consumables. You can apply at any time through your MRCT Business Manager and can expect a quick decision as our DGF panel meets monthly.

The screenshot shows a web browser window with the URL [http://openinnovation.gsk.com/?utm\\_source=Science+...](http://openinnovation.gsk.com/?utm_source=Science+...). The browser's address bar and tabs are visible at the top. The main content area features a large banner with the text "Discovery Fast Track Competition" and a group of scientists. Below the banner, there is a navigation menu on the left, a main content area with the heading "Your idea. Our resources.", and a sidebar on the right with a "Submit a Proposal" button and "Competition News" section.

**Discovery Fast Track Competition**

You could win an opportunity to partner with GSK—helping to develop new medicines from your innovative ideas. Collaborate with GSK drug discovery scientists.

**Overview**

- How Will I Benefit?
- What Are We Looking For?
- How Does the Competition Work?
- What Capabilities Does GSK Contribute?
- How Is IP Safeguarded?
- What Do TTOs Need to Know?

**Your idea. Our resources.**

Do you have a drug discovery concept? Are you a principal investigator affiliated with a U.S. or Canadian research institute, college or university? Are you excited about partnering with a leading pharmaceutical company to translate your novel science into a new medicine?

**If so, the Discovery Fast Track competition is for you.**

**A winning concept.**

Tell us about your concept. Our expert panel of judges will evaluate each submission, selecting up to ten winners.

**Submit a Proposal**

To get details, review forms or receive updates, log in or create your new account.

**Competition News**

Sign up to get announcements from Discovery Fast Track.

FIRST NAME \*

LAST NAME \*

INSTITUTION



- Not-for-profit organization
- Affiliated academic partners
- Scientific expertise & infrastructure
- Access to non-dilutive capital
- No claims on original IP
- Commercialization vehicle
- First rights to negotiate for technologies in CDRD
- Encapsulates and manages IP
- Business focus and expertise
- Preferred access to CDRD's scientific infrastructure
- CVI's share of profits returned to CDRD



## CDRD's Mandate

**CDRD** was specifically created to de-risk promising discoveries stemming from publicly-funded academic health research, and transform them into commercially viable opportunities for the private sector....



The **Private Sector** is then responsible (and much better positioned) to develop them into new treatments for patients

And **Government** realizes the maximum economic and societal ROI....and re-invests back into research

- National not-for-profit drug development, translation and commercialization centre
- Provides specialized expertise and infrastructure
- Conducts critical proof-of-concept studies
- Bridges the commercialization gap between academia and industry....  
...and ultimately, patients



## Initial Project Selection - CDRD

### Key requirements:

- ✓ Willing and engaged Principal Investigator(s)
- ✓ Excellent, innovative science
- ✓ The potential to address an unmet medical need
- ✓ The potential for a solid IP position
- ✓ The potential to be commercialized
- ✓ Critical question(s) / experiment(s) can be identified
- ✓ Fit with CDRD's capabilities and capacity
- ✓ Fit within the strategic vision of CDRD

## CDRD: Translating Academic Discoveries Into New Medicines

