**IMPERIAL COLLEGE INVENTION DISCLOSURE FORM v1.0**

**(to be recorded by relevant Faculty’s INDUSTRY PARTNERSHIPS AND COMMERCIALISATION Team)**

**TITLE OF INVENTION:**

**KEYWORDS (up to 10):**

**INVENTOR(S):**

**FACULTY/FACULTIES / ORGANISATION:**

**DEPARTMENT(S):**

**DISCLOSURE DATE**:

**This form is designed to capture the initial details of inventions made at Imperial College London. Information provided will be used to assess the commercial potential and patentability of the invention.**

***FoE disclosures: It is recommended that you discuss your invention or idea with your Enterprise Champion, your IPC Engineering focal point and/or the Associate Dean Enterprise.***

**PART A: INVENTOR DETAILS**

**INVENTOR(S)**

|  |  |  |
| --- | --- | --- |
| Name | % inventive contribution | Company or affiliation if not College |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
| Total | 100% |  |

**Details of HR Status during the inventive period**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Division and Faculty (or company / affiliation if you were not an Imperial employee for a period of time) | HR status  (eg employee,  visiting researcher, Emeritus Professor, student) | Funding source for employment  (cost centre and account code) | Date From: | Date To: |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

**PART B: Details of Research Funding and ENCUMBRANCES**

|  |  |  |  |
| --- | --- | --- | --- |
| Funding Source  (Cost centre-Account code) | Principal Investigator | Funder | Title of Grant / Research Contract |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Details of Materials Transfer and other Agreements:**

Please give (i) details of any agreements that have been executed which may give rise to restrictions on the commercial use of inventions arising, e.g., relating to materials or software provided under a transfer or license from a third party; and (ii) details of any rights to the invention that arise through industrial or third party support of the research that led to the invention, if not already listed above.

**PART C: THE INVENTION:**

(Please attach further papers as required)

**C.1 Technology**

1. How does it work (in lay terms)?
2. What problem does it solve? Please see Appendix 1
3. How is it unique? To be patentable, inventive steps (i.e., non-obvious steps which are crucial in obtaining the benefits of the invention) must be clearly shown. Please highlight any such inventive steps here. Please see Appendix 2
4. What does the invention do over and above existing technologies?

**C.2 Commercial Potential**

* 1. Who might be interested commercially in the technology?
  2. Do you have any thoughts on whether it would be best as a spinout company or licence deal? Please note that it is rare for an existing medical device company to licence an early stage technology with no clinical trial data.
  3. Competition – can you identify competitor technology? What differentiates your idea?
  4. Do you have thoughts on how money might be made from it e.g.
     1. Selling hardware
     2. Licensing production
     3. Selling/licensing software
     4. Support services
  5. Have you discussed the ideas with anyone internal to College e.g. department academic enterprise champion, associate dean for enterprise, IPC staff? (All such discussions with Imperial College staff are automatically covered by confidentiality agreements.) if so what was the outcome of the discussions?
  6. Have you discussed the ideas with anyone external to College and were they covered by confidentiality agreement? What was the outcome of the discussions?
  7. Please list any previous or anticipated disclosure (i.e., any transfer of information to companies or individuals other than Imperial colleagues that was not imparted in confidence) of information that could be of relevance to the invention.
  8. Please list any papers, conference presentations and proceedings, presentations to companies not under confidentiality etc. with dates and full references where appropriate.

**C.3 Development Status**

1. Can you estimate the technology readiness level (TRL)? See Appendix 3
2. Is further research work going on in the area and is it likely to lead to technology enhancements? On what timescale is this likely?
3. Any Clinical Trial /Study? Or anything else.

**BIOENGINEERING PROJECT DETAILS FORM**

**PART D – PRODUCT DESCRIPTION**

This section asks for more details on your product/service vision. Fill this in as much as you can.

Guidance notes are shown in grey, please remove the guidance part when completing the document.

**D1. Detailed technical description and applications**

|  |  |
| --- | --- |
| **Item** | **Details** |
| 1. **Detailed technical description** | Continuing from part C1a, describe your invention in enough detail so that another bioengineer could understand it and would know how to make it work. It is useful to be mindful of the format of patent claims in writing this description. Refer to Appendix 2. |
| 1. **What Biomedical applications do you envisage?** | List the potential applications you see |
| 1. **Are there potential applications areas foreseen outside of Biomedical?** | List the potential applications you see |

**D2 – Need statement / Product Description**

Duplicate this table and complete for each identified unmet need that you would like to target:

| **Item** | **Details** |
| --- | --- |
| 1. **Need statement – Unmet need** | This should be a simple/clear statement, putting the product/technology in its context and focusing on key benefits, and specifying the unmet need.  For healthcare products, see Appendix 1. Need statement example:  “a way to address [problem] in [population] that [outcome] “. Example, a way to reduce the incidence of urinary tract infections in ICU patients that reduces hospital stay”  “Technology to reduce high blood pressure” is not interesting, “Technology to reduce blood pressure in patients who don’t respond to hypertension drugs” is interesting |
| 1. **What is the size of the problem?** | Search data for the specific countries/market you are targeting. For medical devices to be released in UK/Europe, it makes sense to consider the US as well as Europe/UK. Through internet searches, look for example for the number of people affected, the number of GP appointments, number of lost working days, cost to Health services, reimbursement (see Appendix 4), and/or other healthcare providers/stakeholders worldwide (eg private healthcare) as applicable, the cost to the customer and include the references you have found. |
| 1. **Describe the product(s)/application(s) you envisage in detail? How is it used?** | Describe the product as you envisage it or describe how the technology could be used in industry or in a clinical setting. Be specific. Sketches are ok.  For each product, describe how it is used, for example the introduction method as you envisage for a medical device. Justify why you think this would work.  Do you need to change existing pathways? |
| 1. **Who would use it and where?** | For example, “the implant device would be implanted by an orthopaedic surgeon in NHS hospital using a set of instruments provided. The implanted devices survivorship is expected to meet the gold standard (95% survivorship at 10 years)”. Or “the wearable device would be set up by a physiotherapist, at the initial appointment, and worn by the patients during daily exercises by the patient, for the course of rehab (eg 3 months)”.  . |
| 1. **What is the regulatory framework for the product?** | For healthcare products, describe the likely regulatory approach (e.g. PMA of 510(k), product type/class (note that a device may be regulated as a drug) if you know this. A discussion with a regulatory expert might be helpful.  <http://www.oxfordglobalguidance.com> and  <https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device>  provide useful guidance. |
| 1. **What size is the market and what are its characteristics?** | Through internet searches, identify the market and its size. This section and the next are interlinked, so complete both in parallel.  A good example: <https://www.gminsights.com/industry-analysis/total-knee-replacement-market>.  For the US market, see Appendix 4 |
| 1. **Who is the competition, and how is your product/technology differentiated?** | Continuing from part C1d, quote product names and manufacturers. Use up to date data from recent internet searches. Explain how you are innovative and different (safer, more effective, faster, cheaper, more accurate, superior technology because). Report on current procedure/product costs (a NICE guidance search can be valuable for the UK market). The tables provided below can help guide a competitor’s review if differentiation is not clear. |
| 1. **What do you think customers would need to see/hear in order to change away from competitors or adopt a new technology/cost?** | What data do you think are required in order to demonstrate “better performance”? |
| 1. **Project Sponsor** | Have you got links/agreement in place with potential partners?  List any clinicians/users who really want this product and are guiding its specification.  List the companies who you think might be interested in the technology. |
| 1. **IP search** | Continuing from part C1d, and with reference to Appendix 2, describe any patent/research from other groups that may affect your ability to protect your invention or to commercialise it (i.e. similar technology).  Have you performed a patent search? Performing a patent search on Espacenet/Google patent search can be helpful. To do this, using one of those search engines, capture the search terms, exclusions, search limits and the number of hits at each step of your search. By careful selection of the search criteria, aim to reduce the results to a manageable number for review. Display the patent Figures in the search results, this will allow you to quickly discard results that are not relevant. List the patents you have found, those that you exclude and why, and for those that are relevant, list the inventors and assignee, and a summary of how your technology differs from what is described (as you understand it). |

Table 1: Review of Competitors

| **Device** | **Manufacturer** | **Image** | **Reference** | **Intended Use** | **Technology** | **Regulatory/CE mark claims** | **Costs** | **Notes /marketing claims/on-going clinical trial/links** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

Table 2: Competitors Feature comparison

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Device type I (eg xx) | Device type II (eg xx) | Device Type III (eg xx) | Do nothing |
| Feature 1 – provides pain relief |  |  |  |  |
| Feature 2 |  |  |  |  |
| Feature 3 |  |  |  |  |
| Feature 4 – Regulatory approvals |  |  |  |  |

APPENDIX 1 – Identifying and validating medical needs

<http://ebiodesign.org/chapter/needs-finding/>

<https://www.nsf.gov/news/special_reports/i-corps/>

(there is an Imperial version for postdocs:  <https://www.imperial.ac.uk/enterprise/staff/techcelerate/>)

APPENDIX 2 – Intellectual property considerations

With regards to any potential Intellectual Property, it is important to understand that Freedom-to-Operate and Patentability are distinct and separate concepts in patent law.  Both are important for making a business case for a medical technology.  More info here:

<https://www.wipo.int/wipo_magazine/en/2005/05/article_0006.html>

<https://en.wikipedia.org/wiki/Patentability>

Here is the typical timeline for patenting:

T = 0:  File UK application.  Cost is usually in the single digit thousands of pounds.  From that point, you can publish, present at conferences, etc.

T = 6 months:  Office action from UK patent office (prior art search and feedback on your claims)

T = 12 months:  File international application, using the UK filing date as your priority date.  Another few thousand pounds.

T = 18 months:  Patent application gets published. At this point or soon after, a strong case for return on investment must have been made.

T = 30 months:  Choose countries in which you would like protection.  Potentially tens of thousands of pounds

Identifying and validating a medical need takes time, so this should be a priority.  The 30 months period goes by quickly!

# APPENDIX 3 – TRL LEVEL

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TRL** | **Therapeutics** | **Medical Devices** | **Diagnostic Tools / Digital Health / Other** | **Other** |
| **1** | Discovery research with potential application addressing a medical need. | Discovery research with potential application addressing a medical need. | Discovery research with potential application addressing a medical need. | Discovery research with potential application addressing a medical need. |
| **2** | Scientific review and generation of research ideas, hypotheses, and experimental designs | Scientific review and generation of research ideas, hypotheses, and experimental designs | Scientific review and generation of research ideas, hypotheses, and experimental designs | Scientific review and generation of research ideas, hypotheses, and experimental designs |
| **3** | Initial product development (e.g. compound screening) through to demonstration of proof-of-concept efficacy for candidate therapeutic in vivo. | Development of a functional prototype through to demonstration of proof-of-concept efficacy for device in vitro and in vivo. | Biomarker quantification studies through to establishing specificity of biomarkers using clinical samples | Development of a functional prototype through to demonstration of proof-of-concept in vitro and in vivo or in a test set. |
| **4** | Safety and toxicity of candidate formulations demonstrated in defined laboratory or animal models (non-GLP) | Efficacy and safety of candidate devices demonstrated in defined laboratory or animal models (non-GLP) | Retrospective and prospective biomarker qualification studies complete, or analytical parameters acquired and optimised. | Proof-of-concept demonstrated to pre-regulatory standard. |
| **5** | Safety and toxicity established to GLP-standards (in animal models) and manufacturing process established at the required scale. | Safety and toxicity established to GLP-standards (in animal models) and manufacturing process established at the required scale. | Assay suited to target clinical setting has been developed and manufacturing process established at the required scale. | Regulatory Characterization of Product and Initiation of Process Development or Manufacturing Process Prior to Clinical Trials |
| **6** | Phase I or equivalent studies in humans to assess drug safety [to completion] | Phase I or equivalent studies in humans to assess device safety [to completion]. | Usability of tools has been established with end user groups in situ or assay parameters have been established with clinical samples [to completion]. | Clinical Refinement:  Phase I or equivalent studies in humans to assess device safety [to completion]. |
| **7** | Phase II or equivalent studies in humans to assess drug efficacy [to completion] | Phase II or equivalent studies to assess efficacy and performance [to completion] | Small-scale or single site evaluation of whether the application of the diagnostic improves clinical outcomes complete [to completion]. | Early Clinical Assessment:  Phase II or equivalent studies to assess efficacy and performance [to completion] |
| **8** | Phase III or equivalent studies and Market Authorisation [to completion] | Phase III or equivalent studies and Market Authorisation and CE marking complete. | Multi-site evaluation of whether the tool improves outcomes complete. Market Authorisation / CE marking achieved. | Late Clinical Evaluation/Market Authorisation |

APPENDIX 4 – US MARKET OPPORTUNITY ESTIMATION

Some initial guidance and suggestions

Identify stakeholders. Bear in mind that the most influential decision makers for commercial device adoption are no longer clinical but reimbursement based. So, try to think through the perspective of

* Patient/clinician
  + Does it save time?
  + Does it permit better outcomes (and when will these be seen – the sooner the better)
  + Does it allow the treatment of a previously untreatable patient population?
  + Is the only device that promises to do this or have they heard the same promises 10 times before?
  + What and who affect outcomes? Even in a procedure with relatively poor outcomes the device performance is likely to only be part of the story
* Hospital/Reimbusement:
  + Why should they change? What evidence will they need to be persuaded that they should invest in change (hint: typically this sis a much higher hurdle than convincing surgeons!)
  + They are running a business. If a procedure adds cost or is not currently used, but becomes successful, what will happen to hospitals f it is widely adopted (“The InFuse Trap”)?
  + Is there any bundling (e.g. financial claw-back for Medicare if a procedure is deemed unsuccessful) for the procedure?

Key questions to ask:

* How would the device be reimbursed in the US Market?
* Look for the CPT codes – these define the reimbursement available for a procedure into which the cost of any device will have to fit
* A good source of coding information is often product brochures (sometimes available online) from major manufacturers which are published to help healthcare professionals to code procedures. These can help if, for example, a top-up can be applied for a procedure when a certain device is used.
* Much US procedure volume data is available online for free – look at the CMS data (e.g. <https://data.medicare.gov/>) which can give a good starting point for market size
* Google is your friend – but to establish price and revenue volume ideally you need multiple shots on goal
* Look for healthcare economic data published in academic journals as these often contain reliable analyses of specific procedures and devices
* What have other companies in the same space done in terms of revenue and market penetration rate?

Process:

* It’s much easier, and more credible, to develop a plan for a better mousetrap
* Conversely, better mousetraps tend to be less interesting for investors
* It is much more compelling to develop an analysis that addresses not just the total market for a device, but one that is segmented by competition and patient need, e.g.:
  + There are 1,000,000 procedure x per annum and current device ASP seems to be $10,000 per procedure – thus total market is $1bn! Sounds great!
  + But there are 5 competitors in the marketplace already, with 3 different technological approaches to the problem. You can only compete against company A and B, who have 5% and 10% of the total market respectively. They both have nationwide salesforces and have 20 other reasons (devices to sell) to the hospitals. This makes access hard and inefficient for you.
  + Of the $150m market your sales force can address, your technology can improve outcomes for only 10% of those patients – 80% do fine with currently available products and 10% would still not improve with your device
  + Which makes the addressable market effectively $15m nationwide… and it’s inefficient to get to. Sounds less great.
* It’s OK to make assumptions where you don’t have data – but be clear about what they are and try to use them to get information from investors and clinicians about how good they are; often they will have heard multiple takes on the same procedure/device and will be comparing what you say to their experience.