Commercialization Standard Operating Procedures (SOP) & Guidance

(June 2024 version)

HONG KONG CENTRE FOR CEREBRO-CARDIOVASCULAR HEALTH ENGINERRING

DISCLAIMER

Table of Contents

Spin-off Companies Guidance

This guidance serves as a checklist of standard procedures and aims to provide a general guidance for project teams that are planning to set up spin-off companies for the purpose of commercializing their products at COCHE. Please refer to the notes for more detailed guidance of each step. Feel free to talk to us if you have any questions regarding spin-off companies.

Pre-Seed Stage

1. *Before setting up Spin-off Companies*

- ☐ Apply for HKSTP Ideation programme
- ☐ Apply for CityU HK Tech 300 Seed Fund
- ☐ Apply for COCHE Young Scientist Grant
- ☐ Proof of Concept
- ☐ Create a business plan
- ☐ Create a strong and diverse team (within and outside of COCHE)
- ☐ Start developing a prototype

Seed Stage

2. *Setting up Spin-off Companies*

- ☐ Choose a company name
- ☐ Design company logo
- ☐ Print business card
- ☐ Set up contact details
- ☐ Set up bank account
- ☐ Appoint a Company Secretary
- ☐ Determine the registered address
- ☐ Create your pitch deck
- ☐ Identify potential investors
- ☐ Apply for COCHE Commercialization Grant

3. *Developing prototype*

- ☐ Conceptual Design & Project Rendering
- ☐ Develop a looks-like prototype (for presentation)
- ☐ Develop a works-like prototype (for demonstration)
- ☐ Manufacture OEM prototype
- ☐ Provisional patent application
- ☐ Pilot studies
- ☐ Product testing and certification
- ☐ Final Validation & Product Launch Preparation
- ☐ Establish a Go-to-Market Strategy
- ☐ Apply for HKSTP Incubation / Incu-Bio programme

Series A Stage

4. *Mass manufacturing*

- ☐ Quality Management Systems (ISO 13485)
- ☐ Choose the right manufacturer
- ☐ Talk to Contract Research Organization (CRO)
- ☐ Regulatory Clearance
- ☐ Design Clinical Trial Protocol
- ☐ Clinical Trials

Suggested vendor

Company Secretary **(for company incorporation and company secretarial service)**	**Accolade** www.accoladegroup.com.hk/en/ **HK Company Registration** www.hkcompanyregistration.com/ **Conpak CPA Ltd.** www.conpak.com/
Company Logo Design	**Shining Design & Solutions Limited** Freelance designer +852 9718 5326 adonchong@gmail.com **Fast Design** www.fastdesign.com.hk **HKDesign Pro** www.hkdesignpro.com
Business Card Printing	**e-print** www.e-print.com.hk/ **Print Shop** www.printshop.hk **JoinPrint** www.joinprint.com.hk
Domain Registration	**Google Domains** https://domains.google/ **Porkbun** www.porkbun.com **Squarespace** https://domains.squarespace.com/ **GoDaddy HK** https://hk.godaddy.com
Product Design	**KOODESIGN** https://www.koodesign.co/ **Studio Dott** https://www.studiodott.be/ **Ponti Design Studio** https://www.andreaponti.com/
Manufacturer	**Vincent Medical** Karon Lo, Director of Business Development https://www.vincentmedical.com/ **Vtech** Sammy Luk, Senior Business Development Manager www.vtech.com

	AML https://www.automatic.com.hk/
Freelancers	**Upwork** https://www.upwork.com **Freehunter** https://www.freeunter.hk **Workeroom** https://www.workeroom.com.hk/ **Fiverr** https://www.fiverr.com/
Patent Attorney	**Jennifer Che** Managing Director, Eagle IP Limited https://www.eagle-ip.com/ jenniferche@eipgroup.asia +852 8101 4006 **Marks & Clerk** https://www.marks-clerk.com/
Contract Research Organization (China)	昆拓信诚医药研发（北京）有限公司 https://www.kuntuo.cn/ 广州九泰药械技术有限公司 http://www.jiutaicro.com/ 泰格捷通（北京）医药科技有限公司 https://www.jtmedical.com/

Useful websites

HKSTP programs
https://www.hkstp.org/what-we-offer/incubation-acceleration-elite-overview/

CityU HK Tech 300
https://www.cityu.edu.hk/hktech300/about-hk-tech-300/hk-tech-300-seed-fund

Company Registry
www.cr.gov.hk

Innovation and Technology Fund
https://www.itf.gov.hk

StartmeupHK
https://www.startmeup.hk/

National Medical Products Administration (NMPA) – Rules for Classification of Medical Devices
http://english.nmpa.gov.cn/2019-10/11/c_415411.htm

FDA – Classify Your Medical Device
https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device

EU MDR – Classification of Medical Device
https://www.emergobyul.com/services/eu-mdr-classification-medical-devices#:~:text=Class%20I%20%E2%80%93%20Provided%20sterile%20and,Class%20III%20(high%20risk)

Hong Kong Medical and Healthcare Device Industries Association
https://www.medicaldevice.org.hk/

Hong Kong Biotechnology Organization (HKBIO)
https://hkbio.org.hk/

1. Before Setting Up Spin-off Companies

Before setting up a company, there are several important factors to consider.

Research and market analysis
Conduct thorough research on your industry, target market, and competitors. Understand the demand for your product or service and identify any gaps or opportunities.

Business plan
Develop a comprehensive business plan that outlines your goals, strategies, financial projections, and marketing plans. A well-structured business plan will serve as a roadmap for your company's success.

Financial planning
Determine your startup costs, funding sources, and financial projections. Create a budget and consider factors such as cash flow, expenses, and potential revenue streams. It's crucial to have a clear understanding of your financial situation before starting a business.

Legal considerations
Choose the appropriate legal structure for your company, such as a sole proprietorship, partnership, or corporation. Register your business with the relevant authorities and obtain any necessary licenses or permits. Consult with a lawyer to ensure compliance with local laws and regulations.

Branding and marketing
Develop a strong brand identity, including a memorable company name, logo, and website. Create a marketing strategy to promote your products or services and reach your target audience. Consider your unique selling proposition and how you will differentiate yourself from competitors.

Team and resources
Determine the skills and expertise needed to run your business effectively. Decide whether you will hire employees or work with contractors and freelancers. Assess your resource needs, such as equipment, technology, and office space.

Risk assessment and contingency planning
Identify potential risks and challenges that may arise in your industry or business. Develop contingency plans to mitigate these risks and ensure business continuity. Consider obtaining appropriate insurance coverage to protect your company.

Networking and mentorship
Build a network of contacts within your industry and seek mentorship from experienced entrepreneurs. Networking can provide valuable insights, support, and potential business opportunities.

Personal readiness
Evaluate your own skills, strengths, and commitment to entrepreneurship. Starting a business requires dedication, perseverance, and a willingness to take risks. Assess your personal readiness and determine if you have the necessary qualities to succeed.

Ongoing Business Planning

Business Core

- Product Concept & Target Product Profile
- Value Proposition
- Strategic Plan
- Operation Plan
- Organization Plan

Research

- Research Plan & Milestone
- Publication Plan

Development

- Product Design
- Proof of Concept
- Continued Product Iteration

Go-to-market

- Marketing Plan
- Market Access Plan
- Sales Force Plan
- Channel Plan
- PR Plan

Supply Chain & Quality

- Prototype, Alpha & Beta Products
- Production Plan & Setup
- QMS
- Logistics

Regulatory Affairs

- Registration Plan
- Compliance Management

Clinical Development

- Pre-clinical Studies & Clinical Trial
- Post-Market Clinical Trial
- Clinical Affairs
- Medical Education

Financial

- Asset Valuation
- Investor Relationships & Fundraising
- Budget Plan
- Business Case

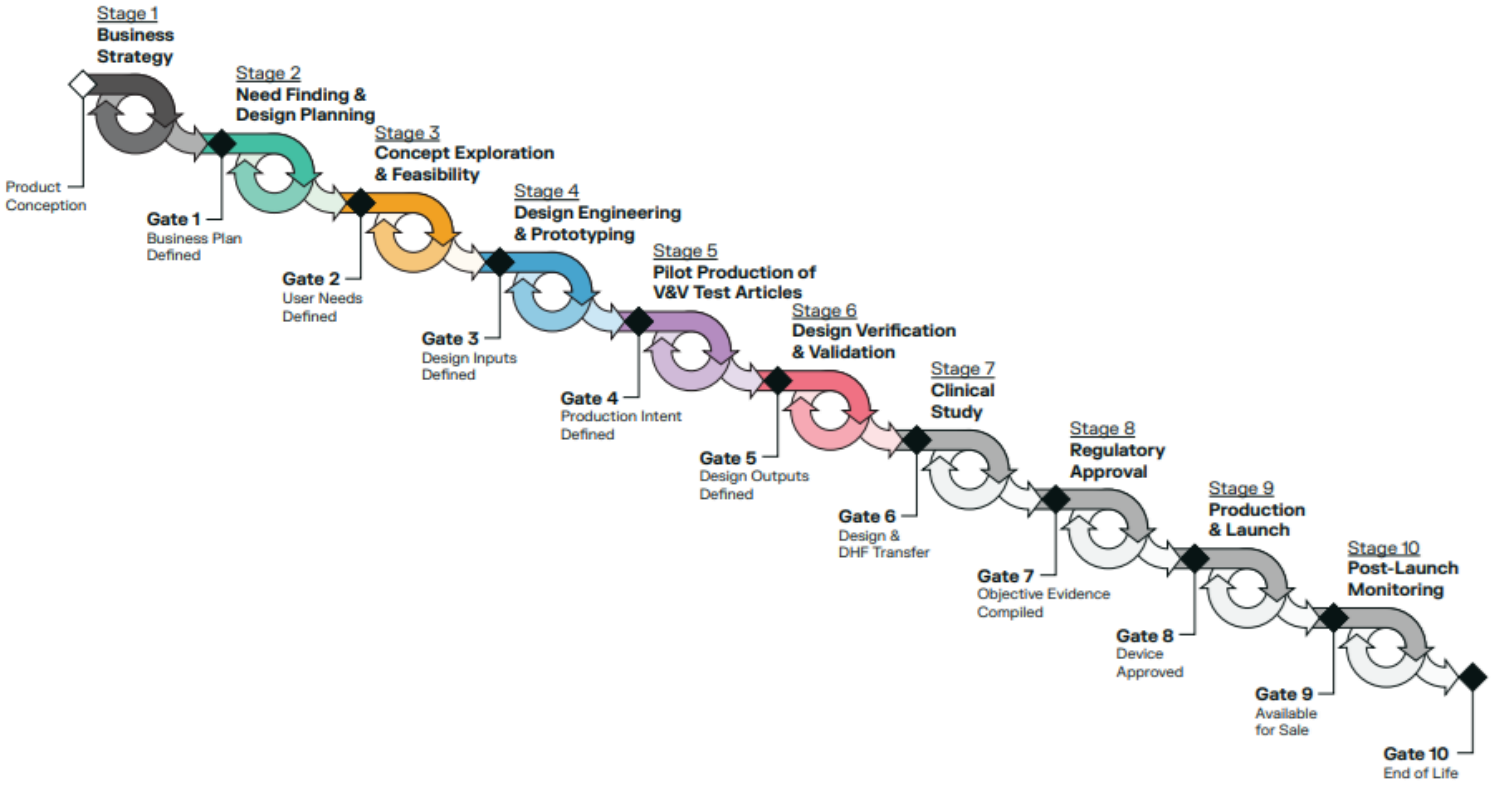
Legal

- Intellectual Property Strategy
- Entity Setup
- Partnership Setup

(Source: Raymond Law: How to Plan My Operations 3)

Medical Device Waterfall Diagram

from product conception to end of life



Delve

Updated January 2024

2. Setting up Spin-off Companies

Below are some basic requirements for setting up Hong Kong companies:

Choose the Type and Name of Company

Choose the type of company that best suits your company's purposes:

- Company limited by shares – the liability of members is limited by the articles of association to the amount unpaid on the shares respectively held by them.
- Company limited by guarantee – no share capital and the liability of members is limited by the articles of association to the amount that the members respectively undertake to contribute to the assets of the company in the event of its being wound up. Non-profit-making organisations are usually registered as guarantee companies.

Then choose a name for the company. The company name must be approved before you can proceed with the incorporation of a Hong Kong company.

Designated Representative

At least one person must be designated as the company's representative ('Designated Representative'). This is the natural person who deals with authorities and law enforcement when it comes to the Significant Controller Register. This individual must be:

- A member (usually a registered shareholder), a director, or an employee of the company, and
- A natural person who is a resident of Hong Kong, and
- A legal professional, an accounting professional, or a Trust and Company Service Provider (TCSP) licensee.

Directors

A minimum of one individual director and unlimited maximum number of directors allowed. The director must be a natural person who can be of any nationality and need not be resident in Hong Kong. Directors must be at least 18 years of age and must not be bankrupt or convicted for any malpractices. There is no requirement for the directors to also be shareholders. Nominee corporate directors can also be appointed in addition to the individual director. Directors Board meetings can be held anywhere in the world.

Shareholders

A Hong Kong private limited company can have a minimum of 1 and maximum of 50 shareholders. There is no residency requirement for shareholders. A director and shareholder can be the same or different person. The shareholder must be at least 18 years of age and can belong to any nationality. The shareholder can be a person or a company. 100% local or foreign shareholding is allowed. Appointment of nominee shareholders is permitted. Shareholders meetings can be held anywhere in the world.

Company Secretary

When setting up a company in Hong Kong, appointing a company secretary is mandatory. The secretary, if an individual, must ordinarily reside in Hong Kong; or if a body corporate, must have its registered

office or a place of business in Hong Kong. It has to be noted that in case of a sole director/shareholder, the same person cannot act as the company secretary. The company secretary is responsible for maintaining the statutory books and records of the company and must also ensure the company's compliance with all statutory requirements. A nominee secretary can be appointed.

Share Capital

Although there is no minimum share capital requirement, the general norm for companies incorporated in Hong Kong is to have at least one shareholder with one ordinary share issued on their formation. Share capital can be expressed in any major currency and is not restricted to the Hong Kong Dollar alone. Shares can be freely transferred, subject to a stamp duty fee. Bearer shares are not allowed.

Registered Address

In order to register a Hong Kong company, you must provide a local Hong Kong address as the registered address of the company. The registered address must be a physical address and cannot be a PO Box.

Business Registration Certificate

The Business Registration Certificate should be renewed, one month before expiry on an annual basis or once every three years, as the case may be.

Ongoing Compliance

It is mandatory for companies to prepare and maintain accounts. Accounts must be audited annually by Certified Public Accountants in Hong Kong. The audited accounts together with tax return must be filed annually with the Inland Revenue Department. Every company is required to file annual returns with the Companies Registry and pay the annual registration fee.

Annual General Meeting

An Annual General Meeting (AGM) should be held annually very calendar year. The AGM should be held within 18 months of the date of incorporation, after which no more than 15 months can elapse between one AGM and the next. A written resolution in lieu of Annual General Meeting is permissible.

Registering a Company Using an Agency

While Hong Kong has greatly simplified the business registration process, the list of documents to be prepared is rather long. And that is not all; some of the documents such as the articles of association can be complex. For those who are overseas, the idea of having to fly all the way to Hong Kong can make the process expensive and complex. The best alternative is using an agency for business registration in Hong Kong.

Company registration agencies in Hong Kong are run by professionals with a lot of experience in business incorporation. They make sure that all the necessary documents are properly prepared for faster registration process. Eventually, the agency can help with complicated documents such as Articles of Association, memorandum of understanding, description of the company's activities, etc. With an agency,

you can focus on other tasks, such as growing the capital to run the company, as the experts take care of the documents.

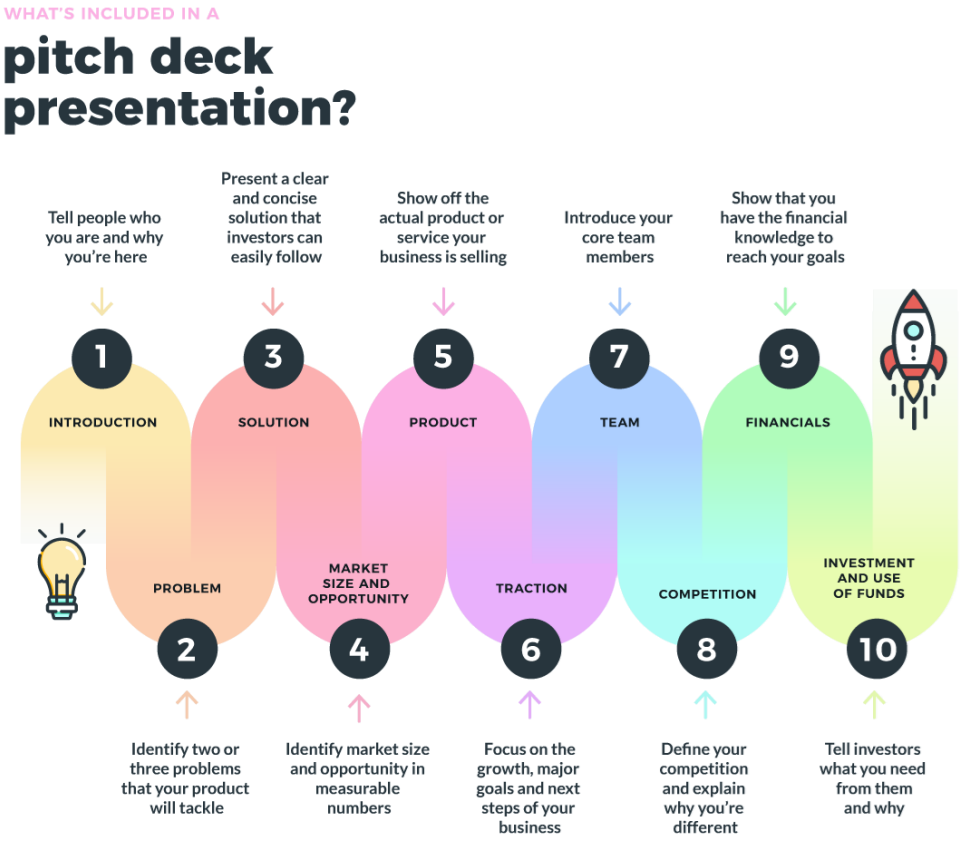
An agency can serve as your company secretary. This is perhaps the main advantage of working with an agency when incorporating a company in Hong Kong. Your company can use the agency's office as its address.

Preparing a pitch deck

A pitch deck is usually a 10-20 slide presentation designed to give a brief and compelling presentation of a new business idea that entrepreneurs give to potential investors, customers, or partners. It's a chance for them to showcase their vision, explain their unique value proposition, and demonstrate their potential for growth.

To create an effective pitch deck, it's crucial to cover a few key points, such as the problem the startup is addressing, the market opportunity it has identified, the team's expertise, and the execution plan. Moreover, highlighting the competitive advantage and potential return on investment can attract investors' attention and interest. A successful pitch can lead to funding, partnerships, and growth opportunities.

Apart from preparing an investor pitch deck presentation or main deck which will be showed when pitching ideas to potential investors, project team could also prepare a shorter version pitch deck or teaser deck that can be sent out to different parties to help generate enough interest for a follow up without overwhelming the recipient with excessive information. Bear in mind teaser decks are aimed at being read by themselves so anyone looking at your teaser should be able to grasp it fully without you presenting it to them and they should be able to cover it in a quick 1-2 minute read. It should cover a quick definition of your problem, solution and market slides. Also, a quick recap of your team as well as your startup's trajectory to date.



(Source: visme.co)

The pitch deck needs to be able to answer the following questions:

1. What problem are you solving?
2. What is your solution?
3. How will you make money? / What is your business model?
4. How big is the market? / What is your total addressable market?
5. Who is your target customer? / Who uses your product?
6. What is your competitive landscape?
7. What is your Go-to-market strategy?
8. What are the risks associated with your business and how do you plan to mitigate them?
9. What is your timeline for achieving key milestone? / What is your product roadmap?
10. What is your team's background and experience?
11. What are your financial projections?
12. What is the ask?

3. Developing Prototype

Developing a prototype for your product is an important step between designing the product and producing it en masse. It is more than a foundational step; it is the bridge between concept and reality. Before you can move on to production, you will need to refine your design and develop a working model. A prototype is also helpful for demonstrating proof of concept, especially when pitching your idea to an investor. It is also a good idea to have the correct intellectual property filed, e.g., a provisional patent application, before showcasing your prototype.

Conduct Research and Concept Development

Research existing devices and technologies in the market to gain insights and identify opportunities for improvement. Develop concepts and brainstorm ideas for your medical device prototype.

Create Design Specifications

Based on the identified problem and concept, create detailed design specifications that outline the functionality, features, and performance requirements of your medical device prototype. Consider factors such as usability, safety, and regulatory compliance.

Prototype Development

Build a physical prototype of your device using appropriate materials and technologies. This prototype should demonstrate the basic functionality and design of the device. Iteratively refine and improve the prototype based on feedback and testing. Determine the materials and tools needed to build the prototype. This may include 3D printing, CNC machining, or other fabrication methods depending on the complexity and requirements of the prototype.

Testing and Evaluation

Conduct thorough testing and evaluation of the prototype to ensure its functionality, performance, and safety. This may involve simulated use, laboratory testing, and user feedback. Identify any issues or areas for improvement and make necessary adjustments.

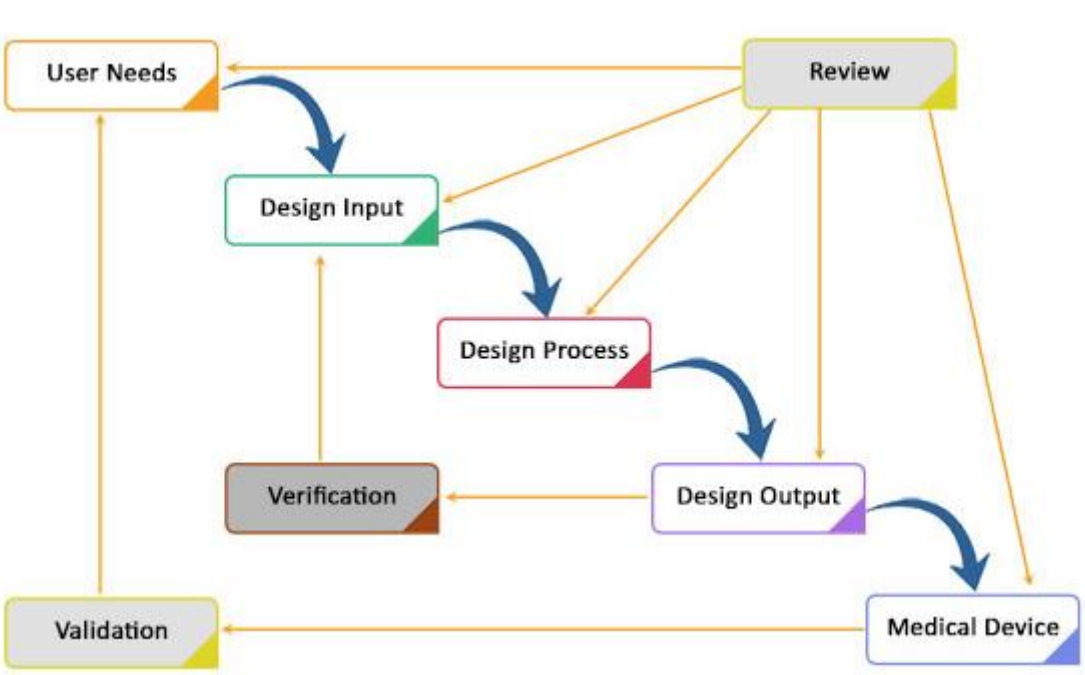
Design Verification and Validation

Verify and validate the design of your device prototype to ensure that it meets the intended requirements and performs as expected. This may involve conducting various tests, including performance testing, reliability testing, and usability testing. Once the prototype meets the desired objectives and requirements, finalize the design and prepare it for presentation or further development. This may involve creating documentation, preparing a presentation, or creating a high-fidelity prototype for demonstration purposes.

Verification and validation of medical devices in the design process aim to ensure that the device is aligned with the need of targeted users and it delivers the intended solution. It also helps ensure whether all the requirements are being satisfied or not. It helps to comply with regulation as well as designing the highest quality product and manufacturing processes.

Verification is internal to internal process, which evaluates whether a design output meets the specified requirements, specification or regulation defined in the design input. Whereas validation is internal to an external process, which evaluates if your product delivers benefits, according to the need of targeted users or not. Medical devices may consist of different technology shapes, sizes, and different level of complexity. Verification and validation (V&V) activity is driven by regulatory environment and must follow international standards.

The image below shows the ongoing process of V&V activity.



Regulatory Landscape

Determine Applicable Regulations

Identify all regulatory bodies and laws relevant to medical devices in your target market, such as NMPA in China, FDA in the U.S. regulating them under Food, Drug, and Cosmetic Act or In Vitro Diagnostic Regulation (IVDR or MDR) in Europe regulating them accordingly.

Classify Your Device

Medical devices can be divided into various risk categories depending on their intended use and potential risks to patients, with each category determining regulatory requirements and levels of scrutiny for market approval. By classifying your device appropriately (Class I, II or III) you can better understand regulatory pathways, conformity assessment procedures and documentation requirements applicable.

Establish a Regulatory Strategy

From early in product development, create an in-depth regulatory strategy plan. This should include all steps and timelines necessary for regulatory compliance such as preclinical testing, clinical studies, quality management system implementation, regulatory submissions etc.

Conduct Preclinical and Clinical Studies

Depending on the risk category of your device, preclinical and clinical studies may be required to demonstrate its safety and efficacy. Preclinical testing includes lab and animal models; while human participation testing occurs during clinical studies. Data generated during these studies provides regulatory submissions with evidence of your device's safety and performance.

Quality Management System (QMS)

Establish and implement an ISO 13485 compliant quality management system in order to comply with processes, design controls, manufacturing, post market surveillance requirements as well as regulatory standards imposed upon your processes and their system requirements – this ensures consistency, traceability and documentation throughout product life cycles.

Prepare Regulatory Submissions

Gather all necessary paperwork and create regulatory submissions for market approval, such as technical files, design dossiers, labelling information, risk analyses and clinical data. Ensure your documents comply with any specific requirements set by regulatory bodies in terms of format, content and process for submissions.

Post-Market Surveillance

Once regulatory clearance or approval is secured, establish post-market surveillance processes to track and report adverse events; conduct clinical follow-up studies post market; as well as create a vigilance system to track device's ongoing safety and performance monitoring.

Keep Current on Regulatory Developments

As regulations for medical devices can change at an ever-increasing pace, stay abreast of any updates or revisions that might impact your device by engaging with industry associations or regulatory agencies as well as attending conferences or webinars to remain aware of new developments and ensure compliance.

4. A) Clinical Studies

To ensure the application for the regulatory process, clinical studies is one of the essential steps. Through clinical studies, you can validate your prototype, and how it works on a subject.

Before conducting a clinical study, you would need to prepare two documents: **(1) Protocol, (2) Consent Forms** (for participants to fill in and acknowledge the use of the data from their clinical trial).

1. Protocol

1. Introduction

- Background of the study.
- Find out the pain points of current existing technology and algorithms.
- Reason for doing the clinical trial.

2. Objective / Hypothesis of your study

- To....
- Can list out “Primary Aim” and “Secondary Aim”
- Can add "Potential Benefits"

3. Research Plan

a) Where is the subject recruited?
e.g., Subjects are recruited from Prince of Wales Hospital, Hong Kong, according to the following schedule.

b) Schedule

- Proposed start date:
- Proposed end date:
- If Longitudinal Studies, specify the follow-up frequency

c) Selection of subjects

- Number of subjects planned
- Inclusion Criteria
- Exclusion Criteria
- Sample Size Justification

Step 1. Check standards/related requirement of the regulation you want to apply for (e.g. FDA) (if any)

Step 2. Find references from research papers and their experimental designs (of similar papers)

Step 3. Estimate it.

Example:

From the previous studies of the assessment of CAD with aortic pulse wave velocity, for each subtype of CAD patients (Control, I-, II-, and III-vessel disease), the average number of patients is up to 23, totally 92(=23x4) subjects [reference paper]. Significant differences in a PWV were observed among the groups, implying that PWV was highly correlated with the severity of CAD. Hence, in this study, we set the sample size to 120 to provide a comparison of PWV and SVA in the CAD arterial stiffening evaluation and blood pressure estimation.

4. Study Protocol

a) Preparation (if any), e.g., avoid eating medicine, rest for 5 min before the start of measurements.

b) Procedures***
- Write in details, so that a 3rd person can read it.
- In steps / Flow charts

5. Reference

a) List out research papers which is related to this clinical study.
b) The usage of the application of the data collected.

6. Ethics

a) Describe if any the risk to the participant.
b) Ensure the protocol is being passed to an ethics approval body.

Example:

Personal data confidentiality will be strictly adhered and each study subject will be assigned a specific study number to replace sensitive personal data for data acquisition and storage. Approval of this study protocol from The University of Hong Kong/Hospital Authority Hong Kong West Institutional Review Board (HKU/HA HKW IRB) will be obtained.

7. Data Handling and Recording Keeping

- Illustrate where and how the data would be kept.

8. Reference

- List out research papers which is related to this clinical study, especially the ones you would refer to illustrate your sample size.

2. Consent Forms *(Official document in English; usually a corresponding Chinese version is also made for layman participants)*

1. ***Introduction***
- Be consistent with the protocol
- Background of the study

2. ***Purpose of the Clinical Research***
- Pain points of the current situation
- The importance and significant of your study to deal with the problems mentioned.
- The benefits and impacts of your project.

3. ***Participation Selection***
- List out the inclusion and exclusion criteria in a layman way.

4. ***Voluntary Participation***
- State that the participant can join at his/her choice

5. ***Procedures and Protocol***
- Write down what instruments used.
- List the steps of the experiments (including rests before the test if necessary)

6. ***Risk***
- Mark down any risks the participant will have.

Example:

The acquisition procedure is non-invasive, painless, and safe for the participants.

7. ***Benefits***
- Write out any further benefits.
- If your protocol has transportation subsidy, please list here.

Example:

There may not be any benefit for you, but your participation is likely to help us find the answer to the research question. There may not be any benefit to society at this stage of the research, but future generations are likely to benefit. If invited participants completed the entire test process, they will receive a coupon equivalent to HKD100 per participant as travel compensation.

8. ***Confidentiality***
- State that the personal data would be saved confidentially.
- Ensure the protocol is being passed to an ethics approval body.

Example (approved by NTEC-CUHK previously)
Your personal data shall be disclosed and processed under the supervision of and by the principal investigator, study team, or authorized parties for the study purposes. NTEC-CUHK cluster REC/IRB is one of the authorized parties to access the subjects' records related to the study for ethics review purpose.

These will be held in strictest confidence under the current HA Policy and Procedure in compliance with Personal Data (Privacy) Ordinance, which will be reviewed from time to time. Your identity will not be disclosed in any future publications of scientific value relating to this study. If you wish to require access to and/or correction of your Personal Data, you may do so under Personal Data (Privacy) Ordinance. Please contact our relevant Data Controller during office hours.

[Contact info, for example:
Address:
Tel.: (852)
Fax: (852)
Email:]

9. *Right to Refuse or Withdraw*

- State that the participant can withdraw at any point of the study.

Example:

You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice, and all your rights will still be respected.

10. *Further information and Contact details:*

- Address the contact point if the participants have any enquiries.

B) Ethical Approval Application Procedures

Any research projects involving human subjects are necessary to obtain research ethics clearance from specific clinical research ethics committees (CRECs), which depends on the location where the research project would be taken place in.

The following are the procedures for applying ethics clearance via hospital CREC (currently COCHE is accessible to The Joint Chinese University of Hong Kong and New Territories East Cluster CREC [The Joint CUHK-NTEC CREC]) and the HKSTP CREC (Hong Kong Science and Technology Park CREC).

Before CREC Application

Discuss with TTCT Clinical Study Team (CST) to decide which CREC body to apply for your project. If your project involves human subjects which needs to be found in hospital, it is suggested to apply via the hospital CREC channel, or else, if your study takes place in HKSTP (or partially taken place in HKSTP), it is suggested to apply via the HKSTP CREC channel.

Complete the Clinical Studies Protocol and Consent Forms (mentioned in Section 4A).

Hospital CREC Application

Time required for hospital CREC Application is roughly 3-4 months. Applications are reviewed on the 15th of every month. Please complete the following step 1 at least 2 weeks prior to the deadline (i.e. 1st of the submission month).

1. Send the Protocol and Consent Forms to CST for approval. CST will give amendment advice if necessary.
2. CST will pass the document to hospital CREC for approval.
3. If amendments needed to be made, the requests will be sent to the applicant.

HKSTP CREC Application

Time required for HKSTP CREC Application is roughly 1-2 months. Applications are reviewed on a bimonthly basis, with deadline on last day of February, April, June, August, October and December. Please complete the following steps 1-2 at least 2 weeks prior to the deadline.

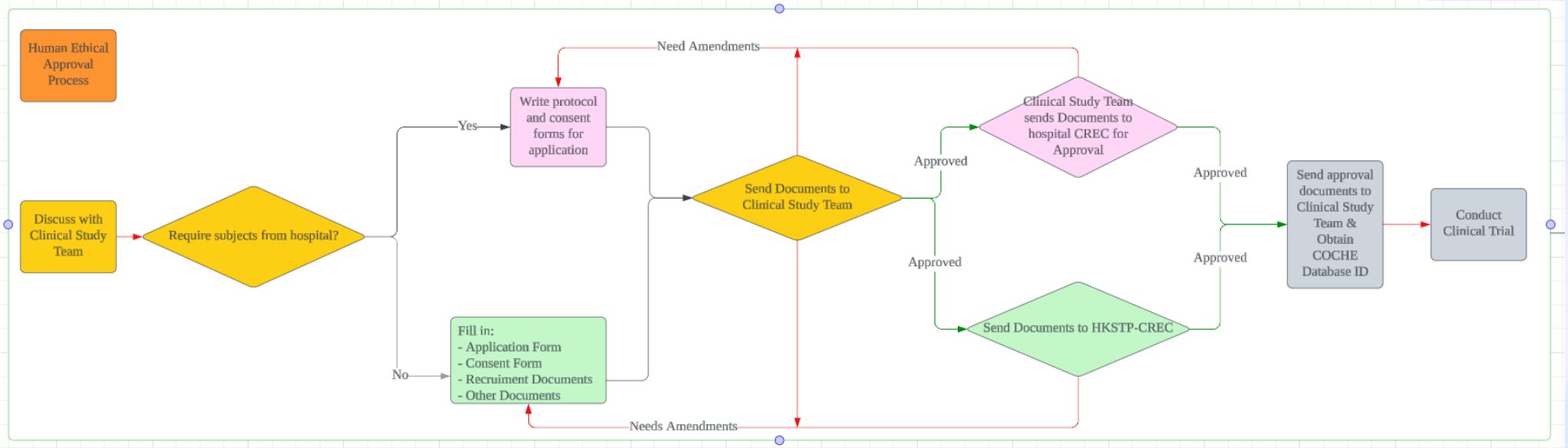
1. Protocol, Consent Forms, Application Form, Recruitment Document (and any necessary document mentioned in the application form) has to be prepared. For recruitment document, it can be an email or poster or any format that can show how human subjects are recruited to your clinical study.
2. Send all required document to CST for approval. CST will give amendment advice if necessary.
3. The document will be passed to HKSTP-CREC by CST or applicant (please cc CST representative for follow-up purpose).
4. If amendments needed to be made, the requests will be sent to the applicant.

After CREC Application Approval

When specific CREC approves your application, an approval email with approval document will be received. Send the approval document to CST and obtain a COCHE Database ID for your project. The COCHE Database ID will be used for naming your subjects. You can start your clinical study. After gathering data, please follow steps for Database Input in Section 10.

Ethics Approval Document Checklist

Documents required	**Hospital CREC**	**HKSTP CREC**
Protocol (with detailed experimental process)	✓	✓
Consent Forms (English & Chinese, if needed)	✓	✓
Application Form [Download from: https://www.hkstp.org/-/media/corpsite/assets/programmes/institute-for-translation-research/iec/crec/2a_appform_for_ethics_review.docx?rev=6e010f99a71040bda687cbd053912187&hash=5B9EE4D418CA8C450E1FBB20591FAEEF]		✓
Recruitment Document (indicating how human subjects are recruited to the clinical study taken place in HKSTP)		✓
Application Checklist [Download from: https://www.hkstp.org/-/media/corpsite/assets/programmes/institute-for-translation-research/iec/crec/2c_crec_appchecklistupdated.docx?rev=a6bf952411e5448495664f9ea00cb123&hash=2C10996E9554FB3A24D6214E8C17FF07]		✓



5. Contract Research Organization

What is a Contract Research Organization?

A medical device contract research organization (CRO) is a specialized service provider that offers support and expertise in conducting clinical trials and other research activities related to medical devices. These organizations work in collaboration with medical device companies, manufacturers, and healthcare institutions to facilitate the development, testing, and regulatory compliance of medical devices.

Medical device CROs provide a wide range of services throughout the different stages of the product lifecycle, from preclinical research and feasibility studies to post-market surveillance and regulatory compliance. Some of the key functions performed by medical device CROs include:

- **Study Design and Protocol Development**: CROs assist in designing clinical studies, developing protocols, and determining the appropriate sample size and patient population for testing the safety and efficacy of medical devices.

- **Regulatory Support**: CROs have expertise in navigating the complex regulatory landscape governing medical devices. They help companies comply with regulatory requirements, such as obtaining necessary approvals from regulatory agencies like the Food and Drug Administration (FDA) in the United States, the European Medicines Agency (EMA) in Europe or National Medical Products Administration (NMPA) in China.

- **Site Selection and Management**: CROs help identify suitable research sites for conducting clinical trials, ensuring that they have the necessary infrastructure, resources, and patient populations required for the study. They also manage site contracts, training, and monitoring activities to ensure compliance with study protocols.

- **Data Collection and Management**: CROs assist in the collection, management, and analysis of data generated during clinical trials. They use electronic data capture systems to ensure accurate and secure data collection.

- **Quality Assurance and Compliance**: CROs help ensure that clinical trials are conducted in adherence to Good Clinical Practice (GCP) guidelines and relevant regulatory standards. They perform quality assurance audits and monitor study activities to maintain compliance.

- **Statistical Analysis and Reporting**: CROs provide statistical analysis and reporting services, including data analysis, interpretation, and preparation of study reports. They help analyse the results of clinical trials and communicate findings to relevant stakeholders.

- **Post-Market Surveillance**: CROs assist in post-market surveillance activities, including monitoring the performance and safety of medical devices once they are commercially available. This helps in identifying any potential adverse events or safety concerns.

By engaging the services of a medical device CRO, companies can benefit from their specialized expertise, infrastructure, and resources, enabling them to navigate the complex landscape of medical device research and development more efficiently and effectively.

Contract Research Organization in China

China has emerged as a significant player in the global medical device industry, and as a result, there are several CROs in China that specialize in medical device research and development. These CROs offer a range of services to support the clinical trials, regulatory compliance, and market entry of medical devices in China and other international markets.

- **Market Expertise**: China medical device CROs have in-depth knowledge of the Chinese healthcare system, regulatory landscape, and market dynamics. They understand the unique requirements and challenges associated with conducting clinical trials and obtaining regulatory approvals in China.

- **Access to Research Sites and Patient Populations:** China's large population and diverse patient pool present opportunities for clinical trials. Medical device CROs in China have established relationships with research sites and access to a wide range of patient populations, allowing for efficient recruitment and enrolment of study participants.

- **Clinical Pathway Strategy**: They help assess the latest NMPA requirements and review your current clinical data to identify the best clinical conformity pathway in China.

- **Clinical Evaluation Report Writing**: They have expert teams with experience writing clinical evaluation reports (CERs) and conducting clinical trials (CTs) to meet Chinese requirements.

- **International Collaboration:** Many China medical device CROs have established collaborations and partnerships with international CROs, research institutions, and medical device companies. These collaborations enable knowledge exchange, access to global expertise, and support for multinational clinical trials.

- **Complete Local Clinical Trial Implementation**: They manage the complete clinical trial process to obtain the final clinical trial report.

- **Product Development Strategy**: They provide strategic advice on product develop.

- **Medical Device Testing**: They conduct testing to ensure the safety and effectiveness of the medical device.

- **Quality System**: They help in establishing and maintaining a quality system for the medical device.

When considering a China medical device CRO, it is important to thoroughly assess their capabilities, expertise, track record, and reputation. Evaluate their experience in conducting clinical trials for medical devices, their understanding of the Chinese regulatory environment, and their ability to meet project timelines and deliver high-quality results. Engaging in open and transparent communication and establishing clear expectations will contribute to a successful partnership with a China medical device CRO.

Key Factors to Consider in Selecting a Contract Research Organization

When choosing a medical device CRO, there are several key factors to consider:

- **Expertise and Specialization:** Ensure the CRO has the necessary expertise and specialization in your specific area of interest.
- **Cost Efficiency:** Choose a CRO with a proven history of optimizing resources to save time and money.
- **Regulatory Compliance:** The CRO should have a deep understanding of regulations and ensure your study is conducted in compliance with the stringent rules and requirements set forth by regulatory authorities.
- **Quality of Data:** The CRO should have a reputation for producing reliable and accurate data.
- **Flexibility:** Choose a CRO that is flexible and can scale to meet the evolving needs of your project.
- **Communication and Collaboration:** The CRO should maintain transparent and consistent communication with the client throughout the project.
- **Reputation and Track Record:** The CRO should have a history of successful projects, satisfied clients, a network of trusted and reliable trial sites, and a demonstrated ability to bring new devices to market.
- **Services and Capabilities:** Ensure the CRO's capabilities cover your specific trial needs.
- **Culture Fit:** The company culture of the CRO should match your own.

Remember, the right CRO for you is one that is the best match for your individual study needs. It's important to do thorough research and consider all these factors before making a decision.

Comparison of CRO in China

The table below shows various CROs that COCHE has been in contact with, alongside a comparison between them. Please note that the details provided under "Budget" and "Duration" are for reference only as the actual cost and duration of clinical studies can vary from project to project. For additional information or to connect with one of the CROs please feel free to reach out to Ms. Gabrielle Du of the Clinical Study Team.

Company	Resource	Experience	Budget	Duration
昆拓信诚医药研发（北京）有限公司 **Kun Tuo**, a wholly owned subsidiary of IQVIA	Have both Global and Mainland China (MLC) resources. In cooperation with more than 380 hospitals in MLC (Peking, Shanghai, Guangzhou, Chengdu)	Have experience in 14 types of medical devices (Including Invasive, Imaging, AI, biosensor, IVD devices) and have more than 150 projects' experience in CVD related and wearable devices	• Without clinical trials: RMB300,000 - 500,000 • With clinical trials for one project: RMB2 million+	18-32 months (From primary experiments to final certificate)
广州九泰药械技术有限公司 **Jiu Tai Yao Xie**, a subsidiary of Boji Medical	Focus more on services in Mainland China, in cooperation with more than 700 institutes from more than 40 cities locating throughout MLC.	Have experience in 9 types of medical devices (Including CVD, AI, surgical robot, IVD related devices) and have more than 300 projects' experience in CVD and IVD devices.	• Without clinical trials: Around RMB500,000 • With clinical trials for one project: RMB2-5 million	18 months + (From primary experiments to final certificate)
泰格捷通（北京）医药科技有限公司 **Tigermed-Jyton,** a wholly owned subsidiary of Tigermed	Have both Global and Mainland China (MLC) resources. Have offices in 25 overseas countries and in cooperation with more than 1370 institutes locating throughout MLC.	Have experience in more than 5900 certification projects and 55 innovative medical devices projects.	• Without clinical trials: RMB300,000 - 400,000 • With clinical trials for one project: RMB2-5 million	18 months + (From primary experiments to final certificate)

6. Manufacturing

The manufacturing stage requires a coordination effort among cross-functional teams, including engineers, manufacturing personnel, quality assurance experts, and regulatory specialists. It encompasses several critical aspects ranging from design for manufacturability to quality assurance.

Optimizing the design of the medical device to ensure smooth and efficient production. Furthermore, careful consideration is given to selecting materials that possess the necessary properties and comply with regulatory standards. Sourcing reliable suppliers and establishing a robust supply chain is crucial to ensure consistent material quality and availability.

Once your medical device has reached a stage where individuals can safely use it, the next crucial step involves obtaining approval from the FDA / NMPA / EU-MDR. Before marketing the device for sale, it is necessary to notify the regulatory authorities. The approval process varies depending on the device's risk level. Class III devices represent the highest risk, requiring clinical trials before going for PMA (Premarket Approval). While a small percentage of Class II devices may also necessitate clinical trials, it is not mandatory for all of them. The primary objective here is to demonstrate that the new medical device is effective and safe for its proposed use. It also shows that the quality management system can maintain its safety and effectiveness.

Launch & Post-Market Activities

Once the regulatory authorities clear your product(s) and Quality Management System (QMS), you are ready to enter the market with your product(s). To ensure a successful launch, it is essential to have a validated and verified production plan that guarantees timely delivery, adherence to budget, and, most importantly, the production of safe and high-quality medical devices.

It is crucial to continuously verify that your plan aligns with regulatory requirements. Regular inspections, audits, and spot-checking should be conducted throughout your production and QMS processes. These measures serve as effective means to identify and address issues stemming from batch-to-batch variations.

Once your products are on the market, it is vital to gather data from various stakeholders, including users, patients, hospitals, technical operators, distributors, etc. Regularly analyzing this data is an integral part of the risk management process. Activities such as Post-Market Clinical Follow-Up (PMCF) and Post-Market Surveillance (PMS) ensure the ongoing safety, performance, and durability of the product.

7. Challenges and Opportunities in Medical Device Development

Costs and Funding Constraints

Developing a medical device involves significant research and development expenses. Costs can arise from conducting feasibility studies, prototyping, testing, and obtaining regulatory approvals. Moving from prototype to mass production involves additional costs. Manufacturing medical devices at scale require investments in specialized equipment, facilities, quality control systems, and skilled labor.

Despite these, securing funding for medical device production can be a major obstacle, especially for startups and smaller companies. This may significantly impede progress and hinder the development of innovative medical devices. Careful financial planning, cost optimization strategies, and efficient project management can help mitigate some financial burdens associated with medical device product development.

Regulatory Complexities and Evolving Requirements

Medical devices are subject to strict regulatory frameworks imposed by regulatory bodies. Some major regulations include ISO 13485, ISO 14971, 21 CFR 820, and MDR. Compliance with complex and evolving regulations is a significant challenge for device developers.

Moreover, regulatory bodies frequently update guidelines, standards, and submission requirements. This is a bid to adapt to technological advancements, safety concerns, and changing market dynamics. Staying updated with these changes and ensuring compliance can be demanding, especially for several years of long development cycles.

Manufacturers have a valuable opportunity to optimize their operations and enhance data management practices. This proactive approach fosters efficiency and empowers them to respond effectively during critical situations. By prioritizing seamless coordination and comprehensive risk management, stakeholders can collectively ensure the highest quality, safety, and compliance standards.

Talent and Expertise Shortages

The shortage of talent and expertise encompasses various areas, including skilled engineers, researchers, regulatory professionals, etc. The scarcity of such professionals can hinder the timely and efficient development of innovative medical devices. Lack of talent and expertise can lead to delays in product development, as finding qualified individuals with the necessary knowledge and experience may take time.

It can also result in suboptimal design choices, regulatory compliance issues, and reduced overall product quality. Furthermore, the fast-paced nature of technological advancements in the medical field requires a constant influx of fresh talent and expertise to keep up with the latest developments. Medical device manufacturers can invest in training and development programs to nurture their existing workforce and enhance their skills.

Emerging Technologies and Changing Market Dynamics

The fast-paced evolution of emerging technologies, such as artificial intelligence, the Internet of Things (IoT), and nanotechnology, presents challenges in keeping up with the latest developments. With new technologies comes the need for updated regulatory frameworks. Adhering to evolving regulations and standards can be challenging. It requires continuous monitoring and adaptation to ensure compliance while bringing innovative products to market.

Moreover, medical devices are becoming more interconnected and part of larger healthcare ecosystems. Ensuring seamless integration and interoperability between devices, healthcare systems, and electronic health records becomes a challenge. Therefore, it is important to harness the opportunities these emerging technologies offer to drive growth in medical manufacturing.

8. Future Trends and Opportunities of Medical Device Product Development

Advanced Materials and Manufacturing Process

There is significant promise for medical device development regarding materials and manufacturing processes. Nanotechnology allows the manipulation of materials at the nanoscale, enabling the development of advanced medical-grade plastics with unique properties. Nanomaterials offer increased strength, improved biocompatibility, enhanced drug delivery capabilities, and better electrical conductivity.

Nanotechnology combined with additive manufacturing techniques allows the fabrication of complex medical devices with precise structures and customized designs. 3D printing at the nanoscale level enables the production of patient-specific implants, scaffolds for tissue engineering, and microfluidic devices with intricate geometries. This technology offers greater design flexibility, faster prototyping, and cost-effective production. Other technologies like medical injection molding are also receiving increased recognition.

Personalized Medicine and Precision Therapies

The concept of personalized medicine has grown substantially over the past years, revolutionizing the treatment landscape for numerous diseases. This ongoing progress is set to accelerate further with breakthroughs in genomics. It will empower healthcare professionals with deeper insights into the fundamental origins of illnesses and facilitate customized therapeutic interventions.

Medical products are becoming more sophisticated in analysing individual patient data, such as genetic information, biomarkers, and other relevant parameters. This enables precise disease diagnosis and tailored treatment plans. This approach minimizes the potential side effects of traditional systemic treatments and enhances therapeutic outcomes.

AI and Machine Learning

The influence of artificial intelligence and machine learning has expanded the possibilities for ensuring high-quality patient care. One prominent trend is the application of AI and ML algorithms in medical imaging devices. These technologies can analyse medical images, such as X-rays, CT scans, and MRIs, to aid in detecting and diagnosing diseases.

Another area of opportunity lies in remote patient monitoring and wearable devices. AI and ML algorithms can process real-time patient data collected by wearable devices to monitor vital signs, detect anomalies, and provide personalized insights. This can enable early intervention, continuous monitoring, and improved disease management.

Regulatory Changes

There is an increasing emphasis on regulatory harmonization and global alignment. Regulatory agencies around the world are working towards aligning their requirements and standards. They aim to reduce duplication of efforts and facilitate global market access to medical devices. This trend allows manufacturers to navigate regulatory processes more efficiently and expand their reach to international markets.

Additionally, regulatory authorities are placing increased importance on monitoring medical devices' performance, safety, and effectiveness once they are on the market. This allows manufacturers to collect and analyze real-world data, engage in active surveillance, and continuously improve their products based on post-market feedback.

Globalization and Expanding Markets

Countries with developing healthcare systems are experiencing an increased need for advanced medical technologies to address their evolving healthcare challenges. This opens up new market opportunities for manufacturers who can adapt their products to meet the specific needs of these regions.

Moreover, advancements in communication, transportation, and supply chain management have facilitated the expansion of markets and the distribution of medical devices across borders. Manufacturers can leverage these advancements to establish partnerships and collaborations in new markets.

9. Patent Strategies for Startups

Patent strategies are a series of steps that a company takes in order to secure and position its inventions, innovations, and/or intellectual property. It covers which innovations you select to give patent protection to, which markets you want to protect patents, who you hire to prepare your patent applications, etc.

Unfortunately, "worldwide patents" do not exist.

In today's global market, a product may be designed in one country, manufactured in another or several different locations and ultimately commercialised all over the world. For this reason, it is essential for any company, big or small, to protect their technological innovations in an appropriate way.

It must be remembered that patents, as other Intellectual Property rights, are territorially limited i.e., the exclusive rights granted by a patent are only applicable in the country or region in which it has been filed and granted. The process of protecting an invention usually starts with applying for a patent (or utility model) in the home country or where the invention was developed. However, in a globalised world this may not be enough.

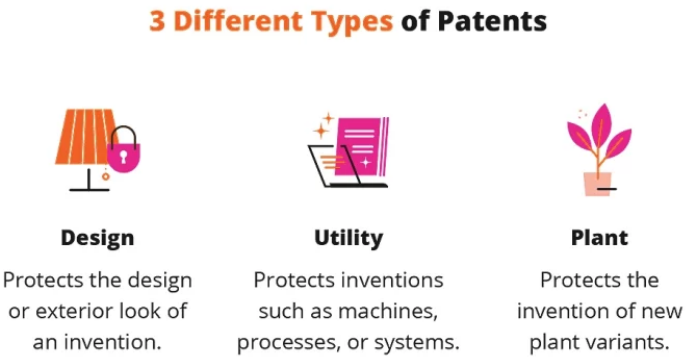
The decision of where to patent an invention, e.g., a new product, depends on various factors, including the following:

- Where will the product be manufactured and commercialised?
- Where the competitors are located and what are their main markets for similar products?
- Do all the countries of potential interest have an appropriate legal system to prevent unauthorised third party exploits of the patent?
- What are the costs associated with patenting in each of the target countries and what is the budget?
- How much income is expected to be received from the commercialisation of the product in that country?

To be patentable, an invention must be **new and inventive** over anything already known at the filing date of the patent application (the so-called "**state of the art**" or "**prior art**"). Since the prior art also includes the inventors' own disclosures, the filing of patent applications related to the same invention has to be coordinated in time across the different countries so that they do not have a detrimental effect on each other. That is, it is not feasible to file a patent application in a given country, and after some years to apply for a patent in other countries, since the publication of the initial application would deprive of validity the subsequent applications due to lack of novelty.

Patent Application in US

Types of Patents



Terms of Patents

Design Patents: For applications filed on or after 13 May 2015, the term is **15 years** from the grant date. For applications filed before 13 May 2015, the term is **14 years** from the grant date.

Utility Patents: Utility patent is generally granted for **20 years** from the date the patent is filed.

Plant Patents: Plant patent is generally granted for **20 years** from the date the patent is filed.

Types of Patent Applications

- Provisional Application
  - A provisional application is a type of application that need not be written in any specific format or require complete information. It is typically filed when the invention is not finalized or is under research process. It is filed in order to claim priority date benefits and preventing others from filing a patent application for a similar invention.

- Non-provisional Application
  - A non-provisional application for a patent filed in the Patent Office without claiming any priority from a patent application made in any convention country or without taking any related reference to any other patent application that may be in process in any office is called an ordinary application or a non-provisional unlike provisional applications, this type of application requires complete specifications and claims.

- Conventional Application
  - A convention application is filed to claim a priority date based on a similar invention and for which application is filed in any of the convention countries. This lets the inventor claim the priority of the convention country for a patent filed in any other country.

- Continuing Patent Application
    - A continuing patent application is a patent application that claims priority to a previously filed patent application. This can include a continuation, divisional, or continuation-in-part application. Continuation allows only amendments to claim, and continuation-in-part applications allow an amendment to claim as well as a description and both are generally available in the United States only. Divisional patent applications require separate filing for an invention that is separate and can be divided and these are also available in other countries also.

- Reissue Application
    - If an applicant or inventor surrenders the patent and re-files the original application to correct the defect such as when the issued patent fails to claim the full scope of the disclosed invention, a patent application is re-issued. This can be done by submitting the patent application again with broader claim scope (no new addition of claims is allowed at this moment) and getting the full coverage.

The best patent procedure for you will be the one that best suits your IP strategy, business plans, budget and goals you intend to reach with your patent portfolio. So, you might say that there is no patent procedure that would suit all companies. However, considering the budget (usually very limited, financial support might only be provided later in the process) and the goals of startups (securing the protection of their products by filing patent applications covering many countries), there is one filing route particularly advantageous for startups: **PCT application**. (For details, please refer to "What is PCT" in the section below.)

Patent Application in China

The laws and regulations governing a China patent require novelty, creativity and practicality for the inventions and utility models applying for patents. The appearance designs shall not be the same as or similar to those that have publicly published on publications in China or overseas or publicly used in China before the application date.

Foreigners, foreign corporations or other foreign organisations without habitual residence or place of business applying for patent in China **must appoint an agent** to carry out the process.

Types of Application

Invention Patent: products, methods or new technical plans proposed for its improvement. Invention patents (similar to a US utility patent) have a term of 20 years from the date of filing and maybe granted for both methods and products.

Utility Model Patent: the shape or the structure of the product or the proposed applicable new technical plans developed from the combination of both. Utility model patents have a term of 10 years from the date of filing and is subject to preliminary examination to check for compliance with formal requirements, novelty, unity of invention and patentable subject matter.

Design Patent: the shape, pattern, color of the product, or the new design which is applicable and may arouse aesthetic sensibilities developed form the combination of them.

Novelty requirements in China are the same for both utility model and invention patents. In particular, novelty means that, before the date of filing, no identical invention or utility model has been publicly disclosed in publications or has been publicly used or made known to the public anywhere in the world. Furthermore, there should be no other earlier-filed applications with the Chinese Patent Office, which describe the identical invention or utility model even if the publication date thereof is after the date of filing of the case of concern.

The advantage of filing a Chinese utility model patent is that the patent right may be obtained within a few months from filing date thereof. For products that have a relatively short product life or have a relatively low technological hurdle (e.g., where competitors may easily reverse engineer and/or copy the technology within a short period of time) a Chinese utility model patent would be ideal. In addition, legal action may be initiated immediately upon grant of the utility model patent. Before taking legal action, however, it should also be noted that an evaluation report of patentability will be required by the court, which serves as prima facie evidence for validity.

On the other hand, Chinese invention patents provide a longer term of protection and are very useful for products that require a longer period of development or that will be commercially valuable for a very longer time. This is particularly true for high technology inventions, such as pharmaceutical and biotech inventions that typically require a lengthy research and development period for the product to be finally registered and put on the market. However, as aforementioned, it will take a comparatively longer time to obtain a granted Chinese invention patent than a utility model patent, and no legal action may be taken during the pendency period. In addition, an invention patent costs more to complete prosecution than that of a utility model patent.

Priority

A patent applicant may enjoy the right of priority, in accordance with any agreement entered into between an oversea country and China or an international treaty under which both of them are parties, for a period of twelve months (six months for Registration of Patent for Appearance Design) immediately from the date on which the initial patent application for the same invention or a utility model was made and such patent application was also made in China.

The following table summarises the differences between invention patents and utility model patents.

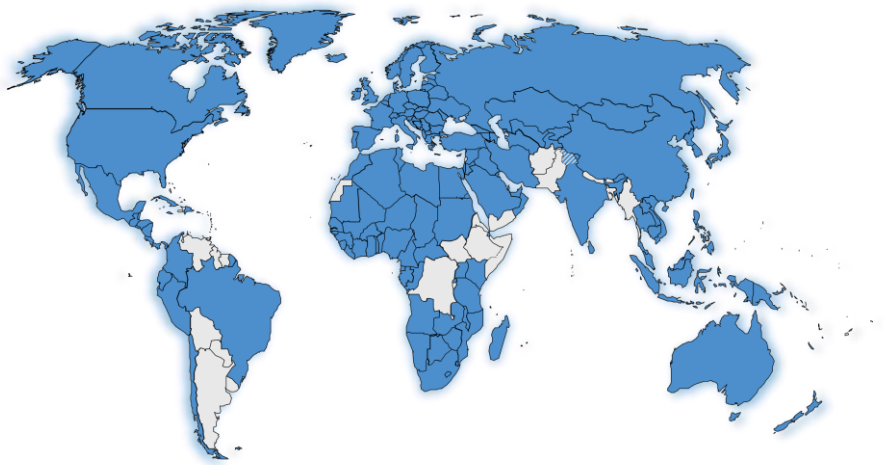
	Invention Patent	Utility Model Patent
Overall Cost	Higher – Filing cost would be similar to that of utility model, but there will be an extra cost for requesting substantive examination. Further costs for patent prosecution such as filing response to office actions will also be required.	Lower – Generally speaking, post-filing costs for utility model are much less than those of an invention application.
Subject Matter	Method, product, composition of matter	Shapes or structures of a product only
Examination	Formality & Substantive Examinations (novelty, inventiveness, sufficient disclosure, unity, etc.)	Preliminary Examination
Novelty Requirement	Yes	Yes
Inventiveness Requirement	Higher (*prominent* substantive features and notable progress)	Lower (substantive features and progress)
Time to Grant	Approximately 3-5 years from filing date	Approximately 12 months from filing date
Terms of Protection	20 years from filing date	10 years from filing date
Assumption of Validity during Patent Litigation	Yes	Yes only if an evaluation report of patentability is procured
Availability of Priority Claim	Paris Convention PCT National Phase Entry (This is typically the application type unless utility model is specified.)[1]	Paris Convention PCT National Phase Entry (Only if specified as utility model during national phase entry.)[1]

[1] For each PCT application entering national phase in China, only one form of patent application can be filed. In other words, the PCT applicant can only choose either an invention patent application or a utility model application but cannot file both types of applications for the same PCT application.

What is PCT?

PCT (Patent Cooperation Treaty) is one of the best things ever created in the world of Intellectual Property. It is also called international patent application (application, not patent!) since it has the broadest geographical scope. However, PCT will not result in a patent itself, so it will not end with an international or worldwide patent.

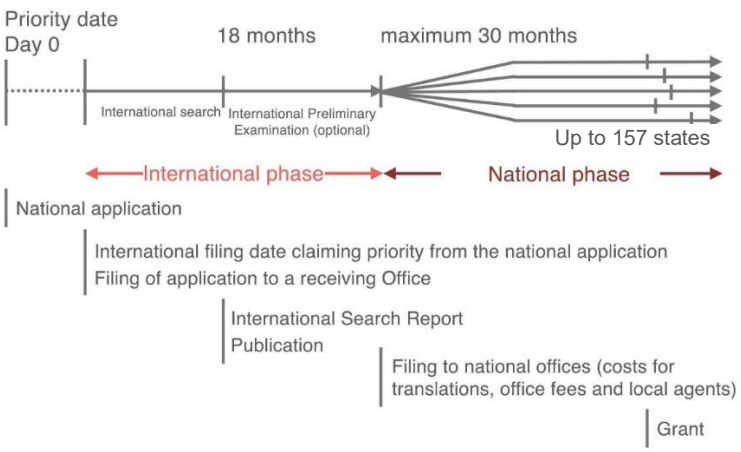
PCT is an international patent law treaty that provides a unified procedure for filing patent applications in up to 157 countries. The member states of PCT are coloured in blue in the map below.



There is unfortunately no such thing as a worldwide patent. In the second part of the PCT procedure you will have to choose any PCT contracting states (states that are members of the PCT agreement) where you would like to obtain a patent. The second part of the PCT procedure is called national phase, where the procedure takes place before the designated patent offices. The PCT procedure will end with a certain number of national patents.

Why startups should file a PCT application?

Startups need a patent application that covers the biggest geographical territory for a limited budget. This is exactly the main benefit of a PCT application. It covers more than 157 countries and to start the procedure, you only need to file a single application in one language and paying one set of fees.



Advantages of PCT:

1. **Cost efficiency**

   Probably the most notable benefit of the PCT is cost efficiency. Of course, there is no free patent application, and a PCT still costs thousands of euros, but patents in general are costly investments. Considering this, the fees of a PCT application offers very good value for money. You can have a patent pending for up to 157 countries by filing a PCT application and paying only one set of fees. (Patent attorney fees will apply as well, but you only need one patent attorney, the other, local patent attorneys should only be instructed 2.5 years later.)

2. **Timing of payments**

   Other than the one set of fees payable at filing (and any patent attorney service fees), there are no more fees you have to pay in the international phase, i.e. in the first 2.5 years. All the other costs, such as the translation and filing fees of the national patent offices that would otherwise occur at filing are only payable when starting the national phase. By that point however, you can raise funds several ways: investors, startup accelerators, etc., or generate income by selling your product.

3. **Allows you to use the phase "patent pending"**

   After filing, you can (and you should) use the expression "patent pending" on your website, in your marketing materials, brochures, or on the product itself as well.

4. **Reassuring investors that protection is secured for a large number of countries**

   Since almost all countries are covered (except Taiwan and Argentina), you can choose any number of countries in the national phase. By filing a PCT application, your invention is secured in all of the PCT member states. PCT is also called international patent application, and you can use this phrase in your marketing materials as well.

5. **Single filing using one patent attorney**

   Filing a single PCT application is much simpler and also less expensive than filing 10-20 patent applications within a short period of time. Should you need a US, a Chinese, a Canadian, a Japanese and an Australian patent, you would have to file 5 separate applications using 5 local patent attorneys. At some point in the PCT (2.5 years after filing) you will have to do the same, but not until that time. In the international phase you only have to pay a single patent attorney's service.

6. **Buy more time**

   One of the most important features of PCT is the first part of the PCT procedure, called "international phase". International phase adds up to 2.5 years to the procedure.

   Basically, by filing a PCT, you are buying more time. You can file a single application and then decide about the countries (any from the PCT contracting states) at a later stage. So, PCT helps you delay both the decision and the respective fees and translation costs.

   In order to decide where you need a patent, you need to know if there is a market for your invention and if so, in which countries. This is an almost impossible task at the time when you are filing your

first application. Furthermore, your invention might already generate some income during the international phase that you can use when starting the national phase.

7. **Looking for investors with an official, positive patentability opinion in you hand**

   During the international phase, you will receive an international search report and a written opinion regarding your invention. These contain important information about the potential patentability of your invention, providing a strong basis for you to make business decisions about how to proceed. If you have a positive patentability opinion, your chances of raising funds for the next steps of the patent procedure are much higher.

Main Routes to Protect in Multiple Countries

There are different options through which an invention may be protected in multiple countries. The four routes shown below are not exclusive but they can be combined in different ways to build a strategy that best suits the applicant's business needs.

1. **Direct or National Route**

   While it is possible to file separate patent applications directly and simultaneously in all of the countries where protection is sought, this process requires a decision at a very early stage for the territories of interest and here are the high costs associated with several filings before several patent offices (translation costs, local attorney and official fees). This strategy can be used when the applicant knows beforehand that he needs protection in only 2-3 countries.

Diagram illustrating the "direct route".

2. **Regional Patent Agreements**

   Thankfully, there are some regional agreements, normally developed by countries belonging to the same region, which allows patents to be granted for all the countries of the agreement. At present, there are five regional patent organisations that grant regional patents:

   - the European Patent Office (EPO),
   - the Eurasian Patent Organization (EAPO),
   - the African Intellectual Property Organization (OAPI),
   - the African Regional Intellectual Property Organization (ARIPO)
   - the Patent Office of Cooperation Council for the Arab States of the Gulf (GCC).

In particular, the EPO administers the European Patent Convention (EPC), a unified processing system for the granting of patents in up to 44 countries from a single patent application. Once granted, European patents have to be validated in each contracting state for which protection is sought in order to be enforceable, resulting in a bundle of individual national patents.

Diagram illustrating the EPC route.

3. Paris Convention Route

Anyone interested in patent coverage in several countries may file an initial patent application or a utility model application (the "priority filing") in a country which is party to the Paris Convention or a member of the World Trade Organisation and subsequently file, within a maximum period of twelve months, one or more applications for the same invention in other Paris Convention or WTO countries **claiming priority from the first application**. The effect of claiming priority is that the subsequent applications are considered to have been filed on the same date as the first application (i.e. priority date), so that only prior art before the priority date is relevant for determining novelty and inventive step.

It is worth mentioning that a patent application may claim priority from more than one earlier application. Therefore, during the priority year the applicant may file additional priority applications with improvements or variations around the same inventive concept as the first application.

Diagram illustrating the "Paris Convention route".

4. PCT Route

The Patent Cooperation Treaty (PCT) is an international treaty that at present covers 157 countries. A full list of the PCT contracting/member states can be accessed here.

The PCT system requires filing just one application, either directly or (most commonly) claiming priority of one or more previous applications for the same invention that were filed up to 12 months earlier. This international or PCT application is processed, searched, and optionally preliminary examined, through a single procedure. It is only after this "international phase", when the applicant must decide in which PCT states protection is required.

This generally happens around 30 or 31 months from the earliest priority date, which is the deadline to enter the "national phase" to file separate national or regional applications in each of the countries or regions where the applicant wants to protect the invention. Each of these national or regional phase applications must be processed independently by the respective national/regional patent offices, who finally grant (or not grant) the patent in their particular territories.

Diagram illustrating the PCT route (with PCT application claiming priority based on the Paris Convention and subsequently being filed with, among others, a regional patent office such as the EPO)

Frequently Asked Questions

Q: Which route should I go for if I want to protect my invention in several countries? Paris Convention or PCT Route?

A: On balance, there are advantages when it comes to the consideration of whether to utilize the Paris Convention or PCT routes for patent filing and protection.

Whilst both routes typically include the filing of a local application with an office of first filing to obtain a priority date, the Paris Convention affords a period of twelve months for applicants to assess which countries they wish to file in before having to commence the national route of protection. The PCT route on the other hand, means that applications won't enter the international phase until 18 months from the date of first filing, and typically take up to 30/31 months, depending on the designated jurisdictions, for the entering of the national phase.

As such, the **Paris route** may be beneficial for those who wish to obtain patent protection in a few countries in a smaller amount of time. On the other hand, the **PCT** may benefit those who wish to make use of a longer time period before they must fulfil the national requirements of the designated states for protection, and to utilize this time period to estimate the chances of successful registration of the invention.

Moreover, whilst the PCT allows for applicants to further file in all PCT signatory member states stemming from the one international application, applicants must file separate, individual applications in the countries of choice if utilizing the Paris route. Additionally, the formality criteria, international search, preliminary reports and international publications are centralized and standardized by the PCT system, whereas the same is not the case when filing through the Paris Convention. It is worth noting, however, that the formal requirements of each member state designated will still need to be met during PCT national phase entry.

The Pros and Cons of Paris Convention and PCT Route:

	Paris Convention	PCT Route
Pros	• Cheaper than PCT filing. • The 12-month convention period allows applicants to seek funding, perform market research, and turn an idea into a commercial product. All of these can be done following a single filing without the risk of losing rights in other countries. • Faster grant approval.	• A single international patent application that allows simultaneous filing for protection in many countries. • Able to check if the application meets the patent grant requirements e.g. novelty, inventive step and industrial applicability. • Once the patent grant requirements are clear, applicants can confidently proceed to file patent applications in other countries of interest. • Applicants have more time (30 or 31 months) to file overseas.
Cons	• Applicants must protect their inventions overseas (in all countries of choice) within 12 months from the date of filing in home country.	• Applicants must pay additional fees for PCT application within 12 months from the date of filing in home country on top of the cost of entering in each country of choice.

Q: Should I First File PCT or US Patent Application?

A: When you need patents in the US and foreign countries, you must eventually file multiple patent applications. The question is which patent application should be filed first. US applicants seeking patents worldwide will often consider filing both a US nonprovisional patent application and an international PCT application. Which application should be filed first? Should both patent applications be filed simultaneously? Let's consider patent strategies for filing US first, PCT first or both concurrently.

When You Are Unsure: File US Patent First and Then PCT

It may make sense to file first in the US if you are not yet sure about international patent protection. Some IP owners know for sure that they want a US utility patent, but have not yet made a decision on foreign patents. Filing your patent application first in the US will give you **one year** to decide on foreign filings assuming there are no priority claims to any earlier patent filings. Filing first in the US will not necessarily give you an advantage in obtaining an earlier allowance of claims. The USPTO still has a long backlog of utility nonprovisional applications to review although the average wait time for the first review has shortened in recent years. It is likely that you may approach the national stage deadline in your PCT application without any allowed claims in your counterpart US application.

When You Want a Granted US Patent ASAP: File US Patent First and Then PCT

Getting the US utility patent granted may be your first and foremost priority. If so, it would make sense to file your US **nonprovisional application** as soon as possible. Once your nonprovisional application is in line, expect to wait about 1.5 to 2 years for the initial examination.

When You Know You Want Foreign Patents: File PCT First and Then US

Filing a PCT application first will give you **30 months** from the priority date to file a national stage application in the US as well as any PCT member countries. Whereas **filing a US application first** gives you **12 months** to file a PCT application.

Filing a PCT application first will enable you to:

- see prior art search results at approximately 16 months from the filing date; and
- amend claims based on the prior art before entering national stages.

The additional time to make claim amendments in response to prior art references found in the PCT prior art search may save money and time in the long run. For example, the applicant can place the US application in a better condition for allowance when it comes time to file US national stage application. Even if the US claims do not get allowed on the first review, the applicant may at least save an Office Action or two.

After Provisional: File PCT and US application concurrently

There may be circumstances warranting the simultaneous filing of both a US and an international application. For example, if a provisional patent application was filed almost a year ago, the applicant may opt to file both the US and international filings by the 1-year deadline.

Filing both applications concurrently **enables the examination of the US application to begin sooner**. More specifically, you keep your earlier place in line at the USPTO which may still be a 15-month wait to the first review by the patent examiner. Meanwhile, an International Search Report may be issued in your PCT application which will show how the claims are allowable or rejected over key prior art references. You can use what you learn from the PCT prior art search to make potential amendments to the US claims prior to the examiner issuing a first Office Action.

After Provisional: File PCT First and Then US National Stage

If you have already filed a provisional patent application, one option is to file only the PCT application by the 1-year anniversary. In contrast to the above approach, filing only the PCT application will still keep the door open for you to file a US national phase application by the national stage deadline. You can even file a bypass CIP application in the US if you need to add new matter that was not sufficiently disclosed in the PCT application. Though this option will keep the door open for obtaining a US patent, **it may prolong USPTO examination** depending upon when you file the US national stage application.

US and Foreign Patent Strategies

Timing and costs are key factors in deciding which patent application to file first. Going first with the PCT may delay the examination of the US application, but could provide greater clarity for claim amendments in the meantime. Filing a US application first can preserve cash flow, especially if you are not sure about seeking international patent protection.

Filing both at the same time gives you the benefit of a prior art search in the PCT application while your US application is awaiting review. If the review of your US application is delayed, which is fairly common, you may have opportunities to file claim amendments prior to the first Office Action based on clues given in your PCT application.

Q: Why startups may want to file a US provisional application?

A: There is a special patent procedure in the US that is also very useful for startups and applicants with limited budget, called "**Provisional application**". If the United States are an important territory for your business already in the first years, you should think about filing a provisional application.

Provisional patent application is a special process, which only exists in the US. It is an **application pending** at the USPTO (United States Patent and Trademark Office) for a non-extendable period of 12 months. It is not examined and not published. If a nonprovisional patent application is not filed by the end of the 12 months, the provisional application dies and cannot be continued.

Q: What is a "Grace Period" of Patent?

A: In general, a patent application for an invention should be filed at the patent office before the invention has been disclosed to the public, because otherwise the disclosure of the invention is "prior art" to the patent application and will be taken into account when considering whether the claimed invention

meets the requirements of being new and inventive. However, some countries operate "**grace periods**" whereby if an applicant files a patent application within a certain time after publicising the invention then the earlier disclosure is not considered to be prior art to the patent application.

The acts of disclosure that can benefit from the grace period vary depending on the jurisdiction and may be limited to certain types of disclosure, for example:

1. disclosure at trade fairs indicated by the patent office
2. disclosure by a third party breaking an information confidentiality agreement, or
3. it can even include any type of act of disclosure by the applicant/inventor.

It is important to note that there is no uniform criterion covering all jurisdictions where this exception exists, and that both the length of the grace period and the type of prior disclosures affected vary by jurisdiction. As there is no common rule in this regard, it is always advisable to apply the criterion of absolute novelty without resorting to the grace period when trying to protect an innovation in several jurisdictions.

Countries that offer grace periods:

Continent	6-month period	12-month period
Europe	Austria, Luxembourg, Germany, United Kingdom	Most countries that are members of the European Patent Convention (EPC)[#]
Asia	China, Hong Kong, Russia	Indonesia, India, Japan, Malaysia, Philippines, South Korea, Singapore, Sri Lanka, Thailand, Vietnam
Africa	Egypt, South Africa	Algeria, Ethiopia, Kenya, Mauritius, Morocco, Mozambique, Uganda, Zambia
Oceania		Australia, New Zealand, Papua New Guinea
North America		United States of America, Canada
South America		Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, El Salvador, Honduras, Mexico, Paraguay, Peru, Uruguay

It should be noted that the offices in South Korea and Japan require the applicant to declare that a prior disclosure has occurred and indicate this disclosure. Such a requirement does not exist in the US.

[#] Many countries of the European Patent Convention, such as Germany, France, the United Kingdom, Italy and Spain, do not offer any grace period for self-disclosures.

Freedom To Operate

Establishing freedom to operate essentially means ensuring that your products and services do not infringe anyone else's Intellectual Property (IP) rights. It is the first step you should take before attempting any marketing. While IP rights include trademarks, utility models and design rights, freedom-to-operate searches mainly concern patents.

Patents are infringed whenever someone carries out any commercial activity that falls within the patent's claims, i.e., its scope of protection. That means the onus is on you to ensure your products and services do not violate other parties' patent rights.

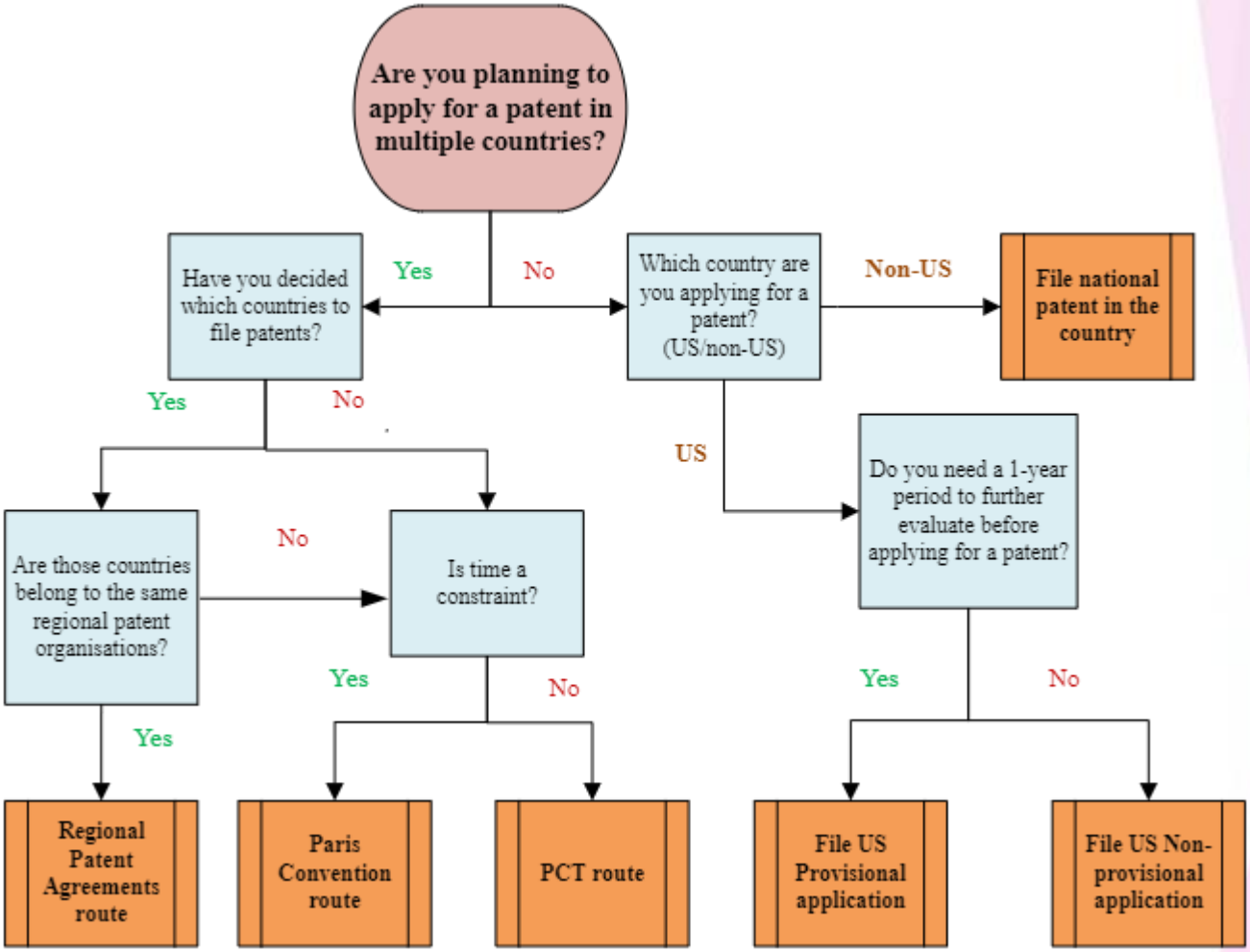
A freedom-to-operate search will therefore establish such information as which relevant IP rights exist and potentially have bearing on your product, the breadth of their protection, where they are valid and for how long, who owns them and any pending legal disputes. It may also recommend any action you should take in response to the findings. The nature of the freedom-to-operate search will depend on the technology involved and the jurisdiction(s) you are doing business in since not all patents are protected in every jurisdiction.

There are several stages in which a company may wish to pursue an FTO:

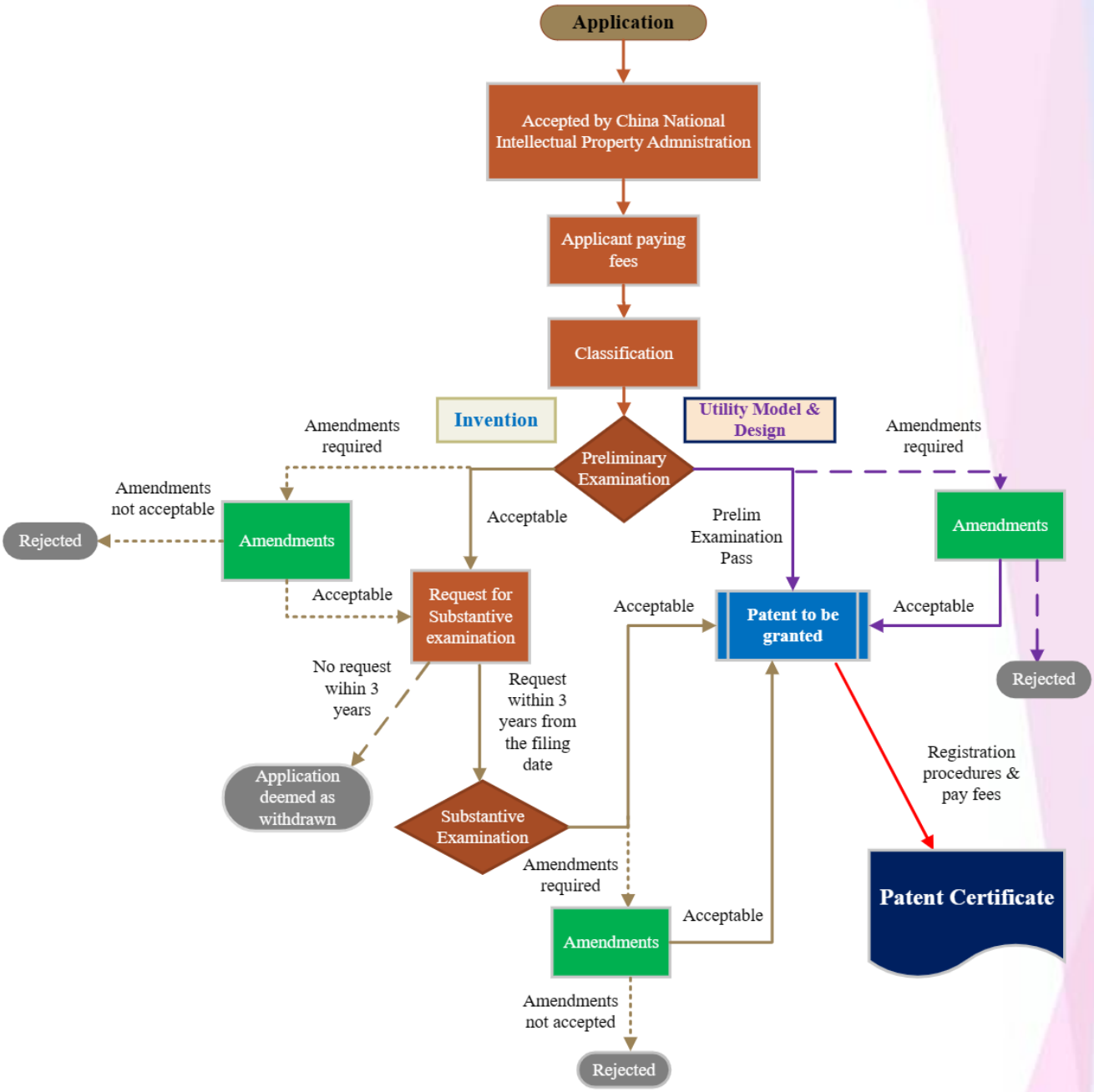
- Before launching products in markets that are particularly crowded, competitive, or litigious;
- Before raising a financing round in which investors will be putting significant sums of money at risk; and
- If the company would suffer severe financial harm if patent litigation resulted in an injunction of its product, process, or service.

Patents are an important part of the commercial value of a startup. It is worth considering what intellectual property your startup has, how it can generate revenue and whether it needs to be protected through patents. Angel investors or venture capital firms may be reluctant to invest in a company unless the intellectual property can be protected with patents.

The decision flowchart below is aimed to help project teams or spin-off companies in deciding which route they could go for when applying for a patent. Remember, patent strategy is not a one-size-fits-all approach. It needs to be tailored to suit the unique circumstances of each startup. Therefore it is crucial to seek professional advice from skilled patent attorney who specializes in your industry in order to leverage patents not only for protection but also as a strategic asset.



Chinese Patent Application Process Flowchart



10. Database Usage Protocol

As part of COCHE your data is invaluable for the ongoing projects in terms of helping to validate output from our medical devices and training our algorithms. You will also have access to the data that other projects have contributed to assist with your projects.

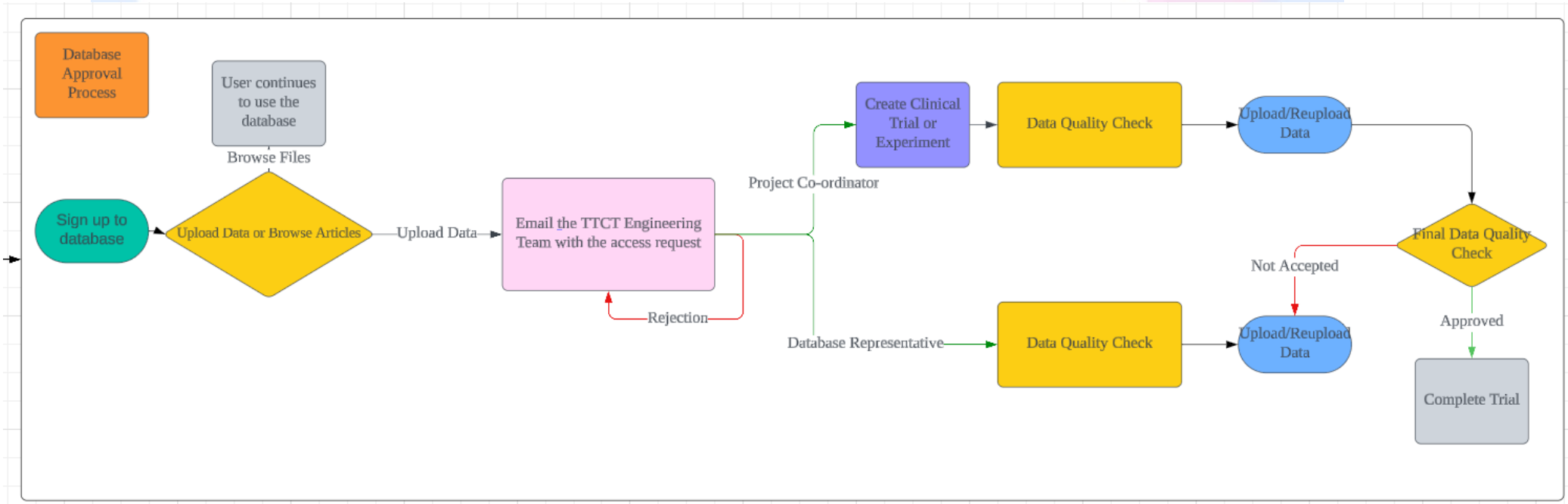
For the database the users will be defined as follows:

- **Project Co-ordinators:** The person leading the clinical trial will be responsible for maintaining data quality, amending data and project access.
- **Database representatives:** The person or people who will be handling the data from the clinical trial responsible for collecting, processing, and uploading the data to the database, and assist the Project Co-ordinator with any data handling.

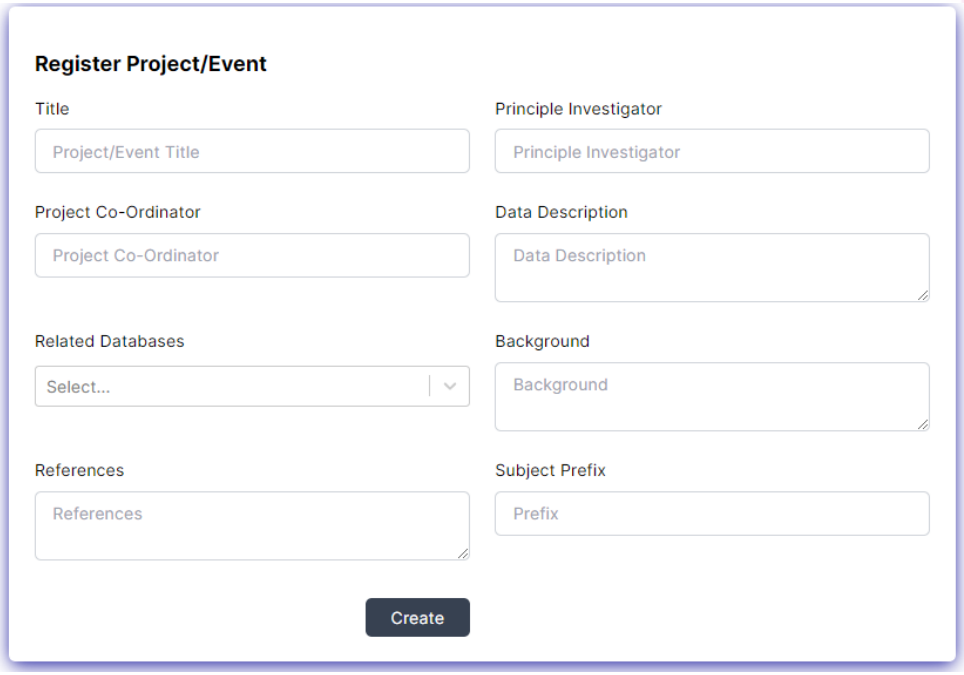
To use the MISSION database the flow chart in the next page summarises the following steps:

1. Sign up to the MISSION Database
2. If you need to add clinical trials and/or data, then email our TTCT Engineering Team with an access request.
3. Once approved as a Project Co-ordinator or a Database Representative, you will be able to upload projects/events and data to the MISSION Database.
4. Project Co-ordinators and Database Representatives will be responsible for verifying the accuracy of the data uploaded for the clinical trial for example assuring the highest quality of signal data or image data.
5. Project Co-ordinator will have the final decision on the quality of the data upload for the project/event.

Database Approval Flowchart



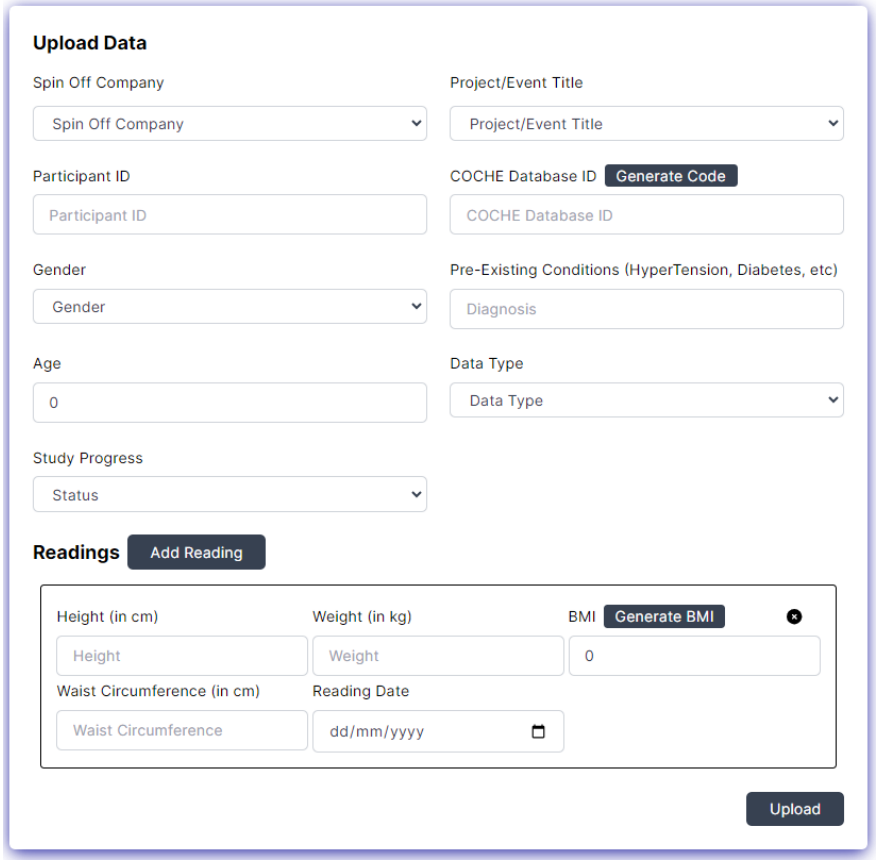
Registering Experiments



For Project Co-ordinators, you can create the clinical trial for storing data.

Title	The name of the clinical trial, project or event
Principle Investigator	The Project Co-ordinators supervisor
Data Description	How the data has been used for the clinical trial and how other researchers can use it
Related Databases	For any related clinical trials that need to be linked.
Background	Why the clinical trial is being carried out, any preliminary information that other research needs to be aware of and the main objective of the trial.

Uploading Data



For Uploading Data, supplementary information will need to be added.

Spin Off Company	The Company conducting the clinical trial
Participant ID	An ID that is unique to one subject, used if the participant has taken part of multiple clinical trials.
Project/Event Title	The clinical trial can be selected from all trials in the database.
COCHE Database ID	Once the Spin Off Company, Experiment Title and Participant ID have been input, the user will be able to generate a unique COCHE Database ID for the project or event.
Pre-existing Conditions	Any pre-existing conditions the subject might have.
Data Type	1D Wave/Time Series, MRI, Ultrasound, etc
Study Progress	Ongoing, Complete, Archived
Readings	The subject height, weight and waist circumference and files will be added as a reading.

Come talk to us!

The Technology Transfer & Commercialization Team (TTCT) has been established with a well-defined team structure comprising a consultancy team, engineering team, clinical study team and project management team. The mission of TTCT is to provide assistance to project teams under COCHE for expediting the commercialization process in order to align the project development timeline with the COCHE's objectives. We aim to accomplish our mission through providing resources and valuable advice to project teams for accelerating their prototype and product development, verifying their invention with clinical data, and ensuring the regulatory compliance during the development process.

If you have any questions or are interested in joining our team, please contact our team members.

Technology Transfer & Commercialization Team Contact List

Consultancy Team	
Dr. Russell CHAN	rwchan@hkcoche.org
Dr. Eddie WONG	ecswong@hkcoche.org
Mr. Jimmy LUI	jchlui@hkcoche.org
Engineering Team	
Mr. Robert CHUNG	rbchung@hkcoche.org
Mr. Lei ZHAO	lzhao@hkcoche.org
Mr. Tanay Kulbhushan AGARWAL	tkagarwal@hkcoche.org
Clinical Study Team	
Ms. Jessica LAU	sklau@hkcoche.org
Ms. Gabrielle DU	jrdu@hkcoche.org
Project Management Team	
Ms. Cathy ZHENG	hmzheng@hkcoche.org
Ms. Thi Trang TRAN	tttran@hkcoche.org