

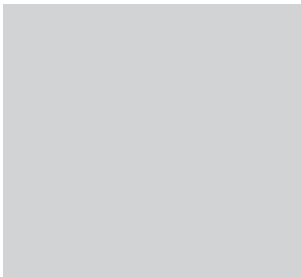


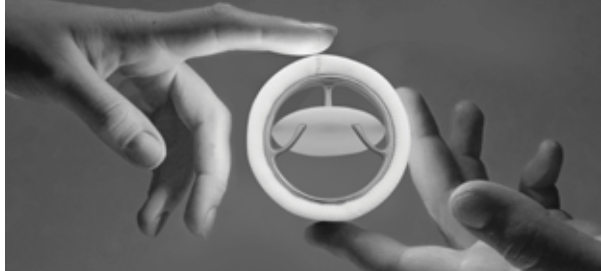
TECHNOLOGY TRANSFER POLICY

BIOMEDICAL TECHNOLOGY WING

INTRODUCTION

The Biomedical Technology Wing (BMTW) of Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), an Institute of National Importance under the Government of India, focuses on development of medical devices and biomaterials for different applications in the field of medicine. The Institute has a long legacy of product development and technology transfer which dates back to 1984 when the first technology was transferred. Following this, the Institute transferred more than 30 technologies to the industry. The Institute has a well established mechanism for technology transfer and the same has been practiced through the years. This policy documents the broad guidelines adopted by SCTIMST with regard to technology transfer.





TECHNOLOGY TRANSFER @ SCTIMST- A POLICY PERSPECTIVE

Scope of this policy:

The scope of this policy includes the entire spectrum of activities from:

1. Identification of technologies for transfer and assessing technology readiness level
2. Marketing efforts for publicising the technologies
3. Identification of potential partners for commercialisation
4. Technology Transfer committee and its role in screening and selecting the most appropriate industrial partner
5. Mode of Technology Transfer
6. Technology Transfer terms and conditions
7. Post transfer support to partner and periodic monitoring

The policy aims to ensure that the maximum number of applied research and technology development projects of the Institute are ultimately transferred to an industry partner for commercial applications, thereby motivating the scientists as well as creating a strong revenue stream back to the Institute for fuelling further research and development activities. This is done transparently considering all relevant techno-commercial factors and by documenting the commitments of the Institute and the Industrial Partner.

Identification of technologies for transfer

Technology is defined as the application of science for industrial or commercial activities. Technology is also defined as the scientific method and material used to achieve a commercial or industrial objective. Whenever a research project shows promise of an industrial application and potential for commercialisation, it is taken up for commercialisation efforts.

Technology Readiness Level (TRL)

The process of technology development may be a long drawn process, spread over several distinct stages. Therefore it is classified into different stages through a method called Technology Readiness Level (TRL). Annexure gives the different TRLs adopted by the Institute.

The lower the TRL level, the lower is the commercial value since the risk is high and more resources are required to complete the project. The higher the TRL level, the greater the chances of success (as more data are available) and therefore, higher the value.

A project at a lower TRL may fetch a lower licensing fee when compared to a project at a higher TRL level, other aspects being the same.

Technology Readiness Assessment Committee (TRAC)

The status of technology including its TRL is assessed by a committee chaired by Head, BMT wing. The committee includes nominated members from the Technical Advisory Committee (TAC), the Ethics Committee (medical devices) and the invited clinical/subject experts.

This committee also identifies the gaps and provides a report of gap analysis for consideration of the project team to take the project closer to what is expected in technology transfer.

The Technology Business Division (TBD) of the institute convenes the meetings and all records are maintained by TBD. The findings are shared with the PI / project team.

Marketing Effort

Timely communication about the intent of Institute seeking industrial partners is crucial to the timely licensing of the technologies. The TBD is primarily responsible for this marketing effort.

A combination of the following is generally adopted:

1. **Presentation and publicising by the Scientists/TBD in conferences**
2. **Preparation of a Technology Profile and making it available on the Institute website, TIMed page**
3. **Mailing the same to associations of industries and Institute's database of industry contacts**
4. **Press release and technical write ups in trade journals**
5. **Updating the standing Technology Compendium on the website**
6. **Exhibitions, Pitching events etc**
7. **Publicising in social media (FB page, Twitter of SCTIMST)**
8. **Publicising on DST website etc**
9. **Seeking potential partners and visiting potential industries**
10. **Engaging consultants and tech transfer firms such as NRDC, CSIR-Tech etc with prior approval**
11. **Advertisement and seeking Expression of Interest from interested partners**



Importance of a partner

The Institute recognises the value and importance of an industrial partner in translating the fruits of research from the laboratory to the market place. Therefore, it places a great importance in selecting a right industrial partner which is capable of overcoming the techno-commercial challenges in bringing a product to the market. The Institute recognises the risk taken by the Industrial partner and therefore is committed to provide support to the partner to the greatest extent possible.

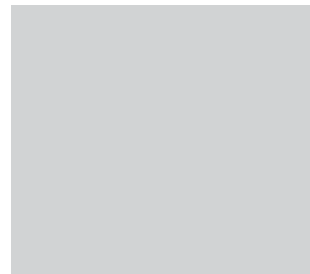
What to look for in a partner?

A project awaiting technology transfer may have certain technical gaps or may need certain specialised skill sets, facilities, processes or materials for its success. In such cases, an industrial partner who provide these missing links either through own resources or by tapping other resources is preferred.

The ability of the industry partner to absorb the technology is another criterion to look for. The partner must have people with requisite skills / educational background to undertake the training and absorb the training in all aspects.

Other things being equal, the Technical strength, R & D capabilities, Manufacturing facilities, Size of the company, Marketing strength, Financial strength, Brand and Reputation etc., is considered.

Depending upon the nature of technology and its TRL / Degree of Difficulty, a small company may have an advantage over a large company and vice versa.



Technology Transfer Committee (TTC) & its role

A standing Technology Transfer Committee is constituted by the Director with Head, BMT wing as chairman, a Technology Transfer Domain Expert (external), two members from Technology Development Committee, Chief Financial Advisor of Institute and Scientist In Charge, Technology Business Division as Member-Secretary & Convener.

The TTC is entrusted with the task of

1. Screening and identifying the most suitable industry partner(s)
2. Recommending the mode of Technology Transfer
3. Recommending the terms and conditions, including deliverables, Institute and industry commitments, financial terms, exclusivity, duration etc.

The Institute clearly defines the TRLs and its commitments to the industry upfront so as to prevent any misunderstanding with the industry partner, that can lead to potential litigations.

In deciding the above, the TTC may consider relevant factors from the following such as

- Technology Readiness Level
- Degree of Difficulty (DoD) of the project
- Nature of innovation- whether incremental or breakthrough
- Mode of transfer
- Deliverables and Institute commitment
- Investment made in the project by Institute as per Technology status document
- Value of patent-residual life, claims, countries covered
- Likely impact of the technology in the market or clinical practice
- Market size, existing competition and barriers to new player
- Challenges to commercialisation likely to be faced by the industrial partner
- Threat of obsolescence
- Number of seriously interested parties



Possible modes of industry tie up and Technology Transfer

Considering the TRL and DoD of a project, different modes of industry tie up and licensing are possible. These may include but not limited to any of the following:

1. Licensing on an as is where is basis
2. Licensing at the current TRL level with consultancy / sponsorship for further development
3. Scaling up / Incubating jointly with the industry partner and licensing post scaling up / incubation to the same partner or to a third party
4. Joint / collaborative project with another research organization and jointly licensing to an industrial partner after completion of the project
5. Undertaking sponsored research and licensing back to the sponsor or a third party

The Financial terms and conditions (also known as valuation)

Determining the financial terms and conditions for transfer of technology to another partner is one of the most important and challenging aspects. There is no readily available rule, formula or framework available that can be applied to arrive at what is worth of the technology or how much should an Institute charge for a technology or what is the best price an industry can afford to pay. Too less a figure will be a loss to Institute and not a real benefit commensurate with the effort and investment put in while too high a figure would not attract interest and also has the risk of making the project unviable. Discovering this figure is an art which involves insights of the parties, backed with data on market size and possible market share for the partner for a certain level of investment.

The main objective of Technology Transfer is to ensure that the fruits of research done in labs are ultimately translated as products in the market. It is also generally understood that excepting breakthrough technologies or instances where the commercial viability is extremely attractive and risks of commercialization are minimal (very high TRLs and minimal regulatory issues), it is rarely possible to recoup investments made in research through a single license. If the technology transferred is successful and is able to get a sizeable market share with a couple of relicensing, it is probable that the royalty earned over a period becomes substantial enough to give a return multiple times the original investment in research.

In general, the financial terms and conditions for technology transfer could be any one or a combination of the following, but not limited to:

• Technology fee as upfront premium

This premium reflects the value of technology / Know-how at the time it is being transferred. The premium being a compensation for the transfer of rights for use of the Know-how, is charged at the time of technology transfer.

For an early stage / low TRL project, that lacks both technology and market validation, thus initial value will be relatively low. For a technology that is close to market / higher TRL and where the Institute has invested heavily in research and spent years to reach that stage, the initial value will be much higher. The lump sum premium may be reduced when the technology is being transferred to a partner that has financially invested in the project or is a sponsor.





- **A royalty payment as a percentage of sales (profit sharing)**

Royalty is an income sharing device compensating for the investment in R&D. Royalties on sales, also referred to as “running royalties” and “earned royalties”, are payments made by the licensee once the licensed products have reached the market place. The Institute (licensor) generally receives a percentage of the licensee’s sales of the licensed products, usually annually, in arrears post sales. Such post-commercialisation payments generally provide the biggest economic return to the licensor from the license if the product is successful. In adopting royalty payment, a number of elements of the royalty provisions need to be negotiated. This includes the royalty base (measurement of sales for which royalty needs to be paid), royalty rate (which could be static, dynamic or sliding) and offsets (discounts etc.), if any.

In calculating the royalty rates, due consideration is given to the nature of technology / product being licensed. In general, for a high value / high technology product, which may have a low sales volume, a high royalty rate is applicable as it is able to absorb a higher royalty rate as the margins and value addition in such products are generally very high. In the case of products with low value / low technology and which are mass produced and highly price sensitive, a higher burden due to higher royalty rate can make the product unviable in the market. In such cases, a lower royalty rate is recommended so as to not make the product noncompetitive in the market. In such projects, even a small royalty rate is justified as the large numbers will make up for lower rates.

To sum up, the percentage royalty rate is a trade off, considering various factors as described above.

In adopting a “royalty only” strategy, there is an inherent risk that if due to any internal or external reasons the licensee stops or is forced to stop production, then the income stream from royalty stops abruptly.

- **An upfront lump sum premium and royalty**

This is an approach which balances the risks of failure with gains of success. The lump sum premium ensures that the partner stays committed and does not leave the commercialization efforts mid way. At the same time, the royalty ensures that the Institute reaps a share of the success of the product over a period of time. It is also known that in case of a success, the royalty returns could be significant with time, as the product increases its market share.

- **Milestone based payments**

Milestone based payments may be negotiated for projects with well defined milestones in the project, such as completion of preclinical evaluation, clinical trials, regulatory approvals, entry to new markets, new clinical applications, achieving certain sales targets etc., wherever feasible.

- **Patent cost reimbursement**

In certain cases, when the cost of patent protection is very high and necessary only for protecting the interest of the licensee, full or partial recovery of the expenses incurred by Institute may be collected from the licensee.

- **Annual minimum Royalty**

An annual minimum royalty may be insisted upon for continued availability of Institute support for trouble shooting and consultations for further improvements in the present technology.

Special opportunities

At times, it is possible that an opportunity may arise wherein the demand for a technology is very high with serious interest from more than one company or when the technology has matured to a high TRL or when the first licensee has made a success thereby making others interested. The above are examples where, there is a possibility for Institute to cash in on the opportunity and earn maximum financial gain. The Institute may then adopt other measures to maximise the opportunity and returns. One such method is inviting competitive bidding by calling for expression of interest (EOI).

Period of license- In arriving at the duration of license period, the following factors are considered:

- In the case of licensing of the patent alone, the royalty is payable up to the life of the patent.
- In the case of licensing of know-how, the royalty is payable as long as the product is in the market.

Nature of License:

The TTC gives a recommendation on the nature of license, whether exclusive to the particular licensee or not. If so, the duration of exclusivity is also recommended by the TTC

- In general, for all projects undertaken through Institute funds or projects from national funding agencies like DST / DBT etc., only non-exclusive licenses are offered
- However, as a part of negotiation, a limited exclusivity for an initial period of maximum of 5 years may be considered, if such a protection is justifiable considering the limited market, competition in market, efforts / investment put in by the licensee etc. in which case it may not be prudent to create another competition for the first licensee
- Apart from the above, exclusivity will require payment of higher license fee
- In case of sponsored project, exclusivity will be as in the Memorandum of Understanding
- For any other convincing or compelling reasons, exclusivity may be granted



Non-exclusivity and Relicensing

In the case of non-exclusive licenses, Institute will continue to pursue and seek industry partners even after the first license has been issued. Similarly, Institute will also actively consider any request for technology transfer after the same has already been transferred. Thus for non-exclusive licenses, relicensing at different point of times or multiple licensing at the same time is possible

However, in all such cases, an explicit willingness and availability of laboratory support for technology transfer will be ascertained. In cases, where in the key personnel has retired or the project team has ceased to work in the same area or laboratory facilities are not available for demonstration and training or if raw materials and special equipment are not available, such projects will be dropped from the list for re-licensing.

In deciding the financial terms, the TTC may also take note of the risk taken by the licensee which is more by the first licensee and less by the subsequent licensees, in case of relicensing, if the first one is successful.

The financial terms may be higher or lower than that of the first licensee depending upon the success or failure of the product post first license.

The TTC is empowered to review the above aspects.

Obligations of Industry partners:

The specific obligations and commitments of Industrial partner is spelt out in the technology transfer license agreements. However, as a policy, the industrial partner is required to always inform the origin of the know-how from the Institute. The industrial partner has an obligation to display the words depicting that the technology is from the Institute in the package and all publicity material.

The design must be with prior consultation and approval from the Institute.

Monitoring post Technology Transfer

As a policy, Institute does not interfere in the affairs or conduct of the business by the industrial partner. However, the partner is bound to provide information that may be sought.

Support to Industry partner

As a policy, Institute supports its industrial partner as long as the product is in the market and industrial partner is making prompt royalty payments. This may be in the form of training and demonstration, sharing technical information, adoption of standards, troubleshooting, advice on testing and quality system, advice on scaling up etc.

Any support beyond what is committed in the agreement will be on a chargeable basis. The Institute offers its testing charges to industrial partners at concessional rates at par with internal customers.

It is also understood that not all technology transfers need to be successful. There may be failures for a variety of reasons, inherent to technology or for totally unrelated factors. In the event of a failure, the industrial partner needs to bear the loss for the investments and efforts put in by the partner's post technology transfer.

APPROVAL OF RECOMMENDATIONS OF TTC

The recommendations of the TTC on the above are placed before the Director for final approval. In all matters connected to Technology Transfer, the Director is the approving authority.



Annexure

TECHNOLOGY READINESS LEVELS

CONCEPT PHASE

TRL 1

- Research Idea
- Shows promising potential application

TRL 2

- Applied Research Idea
- Hypothesis testing and initial proof of concept is demonstrated in a limited number of *in vitro* / *in vivo* trials

TRL 3

- Project plan
- Device Characteristics Document & Project proposal completed
- Ready for Phase I – Proof of Concept (PoC) Phase

PROOF OF CONCEPT PHASE

TRL 4

- Development
- PoC and safety of the device is demonstrated in *in vitro* / *ex-vivo* / *in vivo* conditions

TRL 5

- Standardisation
- Documentation on design transfer, material evaluation matrix and device evaluation matrix completed
- Ready for Phase II – Preclinical Evaluation (PCE) Phase

PRECLINICAL EVALUATION PHASE

TRL 6

- Preclinical evaluation
- Preclinical evaluation completed
- Documentation on Device Master File, Technical Advisory Committee / Ethics Committee, Clinician's Brochure and Clinical Trials Protocol Completed
- Ready for Transfer of Technology (ToT) Phase

TECHNOLOGY TRANSFER PHASE

TRL 7

- Technology Transfer
- Training of industry / Technology transfer completed
- Technology transfer documentation completed
- Ready for Multicentre Clinical Evaluation (MCE) Phase

CLINICAL EVALUATION PHASE

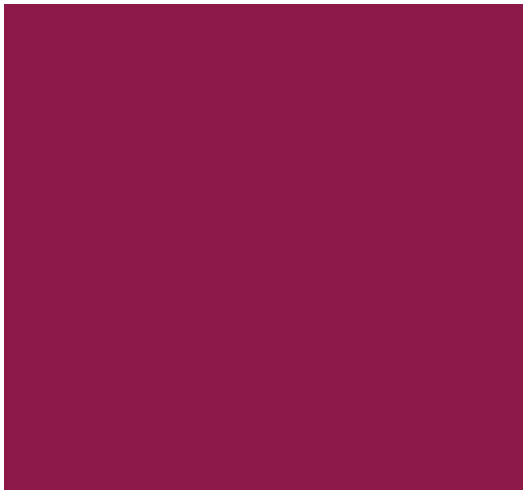
TRL 8

- Clinical evaluation
- Clinical Evaluation Completed
- Documentation on Device History File completed

COMMERCIALIZATION PHASE

TRL 9

- Commercialisation
- Commercialization & Post market surveillance



**SREE CHITRA TIRUNAL INSTITUTE FOR
MEDICAL SCIENCES & TECHNOLOGY**
TRIVANDRUM, KERALA- 695 012, INDIA



www.sctimst.ac.in