Intellectual Property Management at the Indian Council of Medical Research

K. Satyanarayana
Head
Intellectual Property Rights Unit
Indian Council of Medical Research
Department of Health Research , New Delhi
E-mail: kanikaram_s@yahoo.com

ICMR

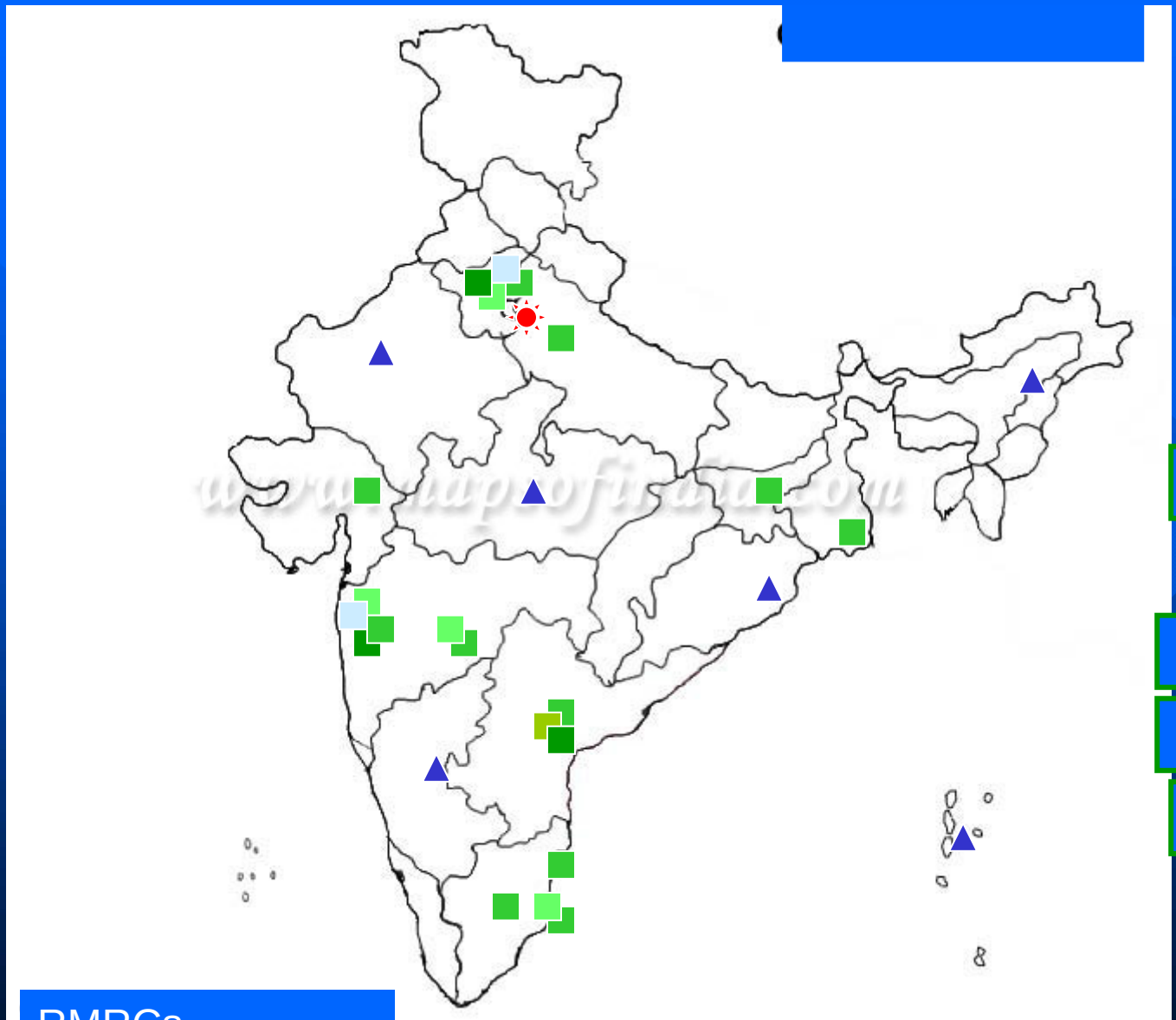
- ICMR is the premier national national organisation for *planning, promoting, co-ordinating* and *conducting* biomedical research in India established in 1911
- To undertake and support basic, epidemiological, applied and operational research in the areas of national public health importance using tools including those of modern biology

Better Health Through Research

ICMR

- Acquire new knowledge through the conduct and support of biomedical research that would have a bearing on improving the health of Indian people
- Carries out its mandate though its 27 Institutes/Centres, extramural research projects and through active industry, and international collaboration

ICMR INSTITUTES



- MRC
- IOP
- IRMS
- ICPO
- NIOH
- IIH
- NIRRH
- EVRC
- GRC
- NIV
- NARI

- HQRS
- CJILMD
- RMRI
- NICED
- NIN
- FDTRC
- NCLAS
- VCRC
- TRC
- NIE
- CRME

RMRCs

RMRC RMRC RMRC RMRC RMRC RMRC

The functions of IPR Unit

- Identification of IP
- Promote awareness of IPR among scientists and encourage quick protection and transfer the industry
- Provide techno-legal support for all new inventions
- Exploiting the IP through licensing
- Facilitate collaborative projects with academia, institutes and industry to generate new IP
- Put products into market
- Work towards the goals and objectives of the organization

Policies for promoting generation/transfer of new IP

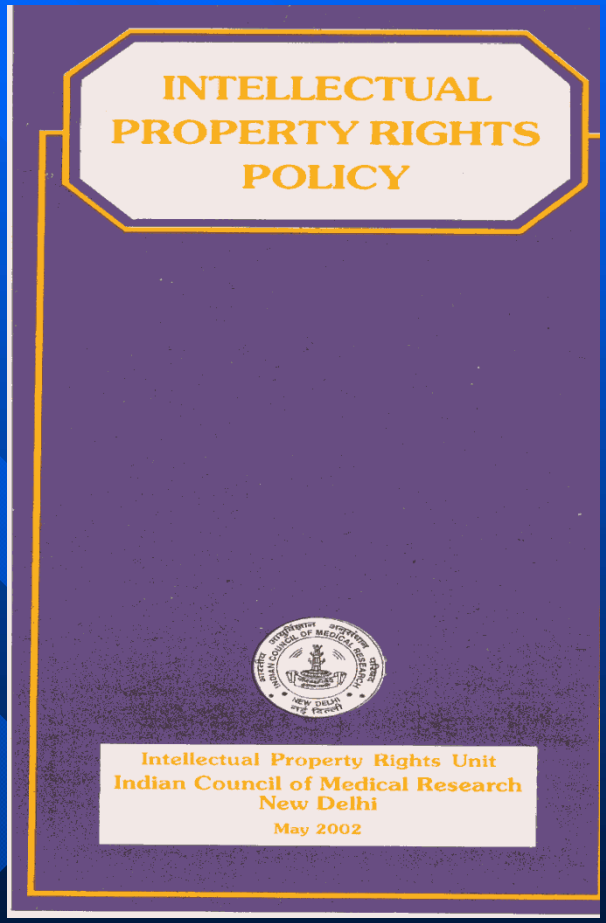
- Material Transfer Policy
- IP Policy
- Technology transfer policy
- Royalty sharing policy
- Licensing agreements

Mission Statement on Intellectual Property

The ICMR recognizes and supports new intellectual property *development* and *technology transfer* as *integral components of its mission* and asserts that the guiding principle governing the conduct of these activities shall be the *prompt and efficient availability of the products* developed for the service of its *mission*

Intellectual Property Rights Policy

The *IPR Policy* of the ICMR formulated by the IPR Unit was released and adapted by the Union Ministry of Health & Family Welfare, Government of India in 2002



IP Policy

- It is based on the principle that the intellectual property generated by an ICMR employee is *owned* by the Council but that any revenue generated is shared with the employee inventor*
- All new IP generated with Council's support belongs to ICMR*
- Patents are filed in the name of scientist(s)/inventor(s) and rights assigned to the ICMR

* only for intramural research

IP Policy

- IP generated with ICMR support in extramural projects by non-ICMR scientists will be *generally owned* by ICMR, but negotiable
- IP generated jointly through institute-industry partnership can be jointly owned through an MOU
- Institute-industry partners could even transfer the technology to a third party for commercialization through licensing
- Royalty sharing by inventors negotiable

Major Objectives

- To develop and implement a royalty policy at ICMR institutions that encourages innovative scientists and technology generators through a system of royalty sharing and reward system
- To create and maintain a database on the patents and other innovations of the Council as also related data

Major Objectives

- To advise the Ministry of Health, Government of Indian government on IP related issues concerning public health
- To forge appropriate strategic alliances with national and international S&T agencies to develop and market its new inventions and develop professional knowledge networks for ICMR's technology management professionals

IP Policy

- Pursue an active policy of ensuring most rapid and efficient availability of new products/technologies developed with ICMR support by seeking of IP right protection within and outside India
- Ensure that as an agency of the Indian government, the *basic mission of research is not compromised* by its efforts to commercialize new technologies

IP Policy

- Where further research and development is not necessary to realize the technology's primary use and future therapeutic, diagnostic or preventive uses, patents may not be sought and instead can be commercialized *through non-patent licensing*
- *In some cases may be put in public domain*

Patent Procedures

- All new inventions of the Council reported to IPR Unit
- Inventions that could be protected will be reported through an Invention Disclosure Form
- Once the IP is found patentable, techno-legal support provided for IP protection
- Filing and maintenance of patents done centrally at the IPR Unit
- All costs borne by the ICMR

Licensing Policy and procedures

- Licensing policy clearly laid down
- Scientists encouraged to have written agreement like MTA before a project is undertaken
- Licensing policy decided on a case-to-case basis
- For industry-sponsored research, MOU drawn up before the project is initiated
- Licensing negotiations done centrally by the IPR Unit
- ICMR retains the right for royalty-free license for Government of India use

HIV/AIDS vaccine

- Establish partnerships to design, develop and evaluate candidate AIDS vaccines appropriate for use in India
- Capacity building, advocacy and training for preparation for the conduct of Phase-I, II and III trials
- Technology transfer, including transfer of manufacturing technology for production by an Indian manufacturer(s)
- Ensure access to such a vaccine(s) in the public sector

Partners

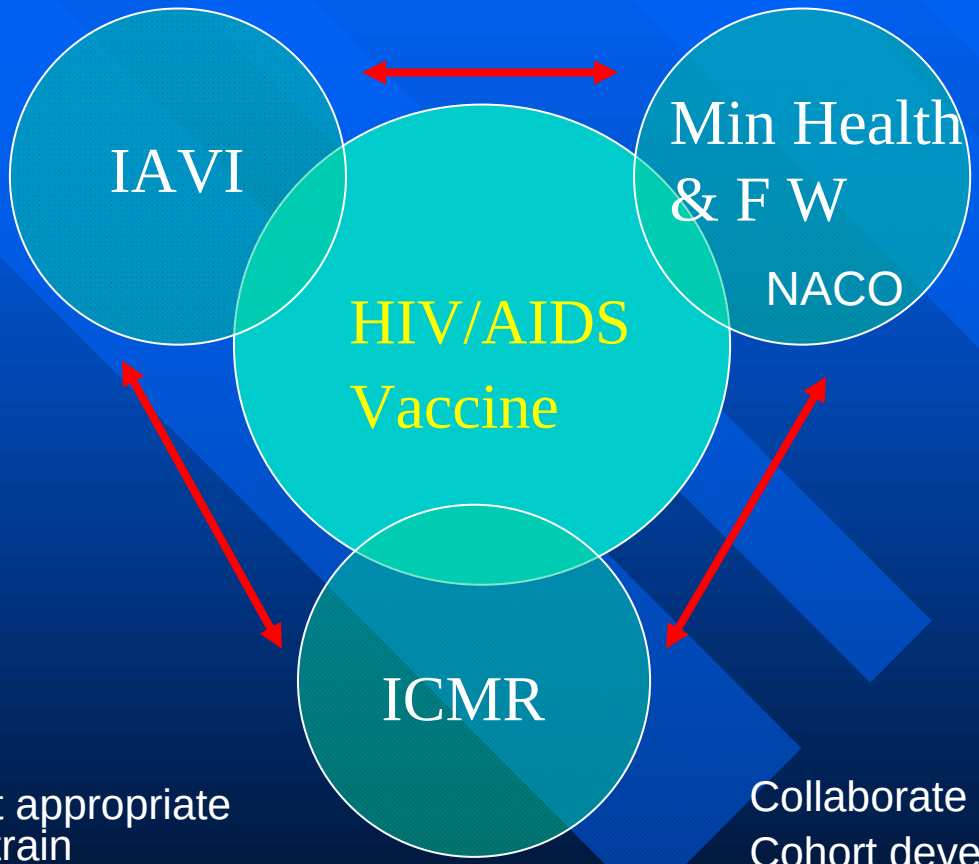
- ICMR- has developed the technical know-how of vaccine development and expertise to conduct clinial trials
- India - GMP facilities for producing world-class vaccines
- Govt of India – approvals, regulatory issues
- IAVI - experience in AIDS vaccine development and evaluation and willing to help
- Willing to support and ‘mediate’ in technology transfer
- Therion - Help ICMR develop the multigenic MVA vaccine (HIV clade C, multigenic, env, Pol, geg, rev, nef and tat)
- Help transfer technology to the Indian manufacturer identified by the Indian government

Role of Partners in HIV Vaccine Development

Design, develop and evaluate candidate vaccines appropriate for India

Capacity building, advocacy, training for vaccine trials

Transfer of technology for manufacture of vaccine in India



Facilitate permissions and permits

Harmonization of goals

Selection of Indian manufacturer

Select appropriate HIV strain

Provide technical expertise

Collaborate in pre-clinical trials

Cohort development

Community preparedness

Conduct clinical trials

New Challenges

- Dual challenge
- Create new knowledge and
  - Protect and exploit
  - Put in public domain – Open access
- IP for public good/ Create wealth?
- Inventors' concerns?
- National obligations – economic development
- Balance – IP rights and public good – National? Global?
- Find the *best* balance?

DNDi IP Policy Statement

"The DNDi's approach will be pragmatic, and decisions regarding the possible acquisition of patents, ownership, and licensing norms will be made on *a case-to-case basis*. DNDi will put the needs of the neglected patients first and will negotiate to obtain the best possible conditions for them. The DNDI's decision regarding IP will contribute to ensuring access and encouraging further innovations"

Banerjee J and Picoul B. Pragmatic and Principled: DNDi's approach to IP Management. In *IP Management in Health and Agricultural Innovation* Eds Anatole et al MIHR/PIPRA , 2007.

Putting TRIPS in context

"Conclusively documenting the benefits or costs of TRIPS for developing countries may be impossible."

Eiss R, Satyanarayana K and Mahoney RT. 2006. Living with TRIPS: Innovation of New Health Technologies for the Poor. *Innovation Strategy Today* 2 (1):13–16. www.biodevelopments.org/innovation/index.htm.

"IP rights are a compromise and an imperfect solution. They represent the search for balance between making all knowledge freely available within the *public domain* and granting *ownership* of valuable discoveries to the inventors. …the public sector can craft effective solutions that can achieve, or at least approach, a suitable balance. This can be accomplished by using the existing IP system …".

Krattiger A, RT Mahoney, L Nelsen, JA Thomson, AB Bennett, K Satyanarayana, GD Graff, C Fernandez and SP Kowalski. 2007. From Best Principles to Best Practice: Message from the Editorial Board. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices (*MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A).

Thank you