



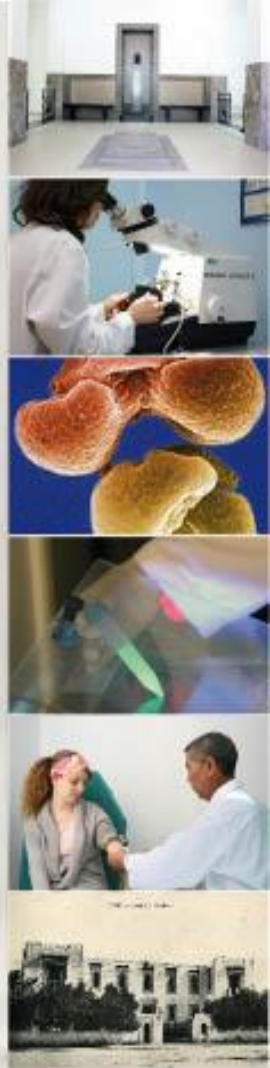
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Sharing Knowledge and Experience on negotiating licensing agreements

Oussama BEN FADHEL

Project Manager in Technology Transfer

*Knowledge Transfer Office, KTO IPT
Institut Pasteur de Tunis*

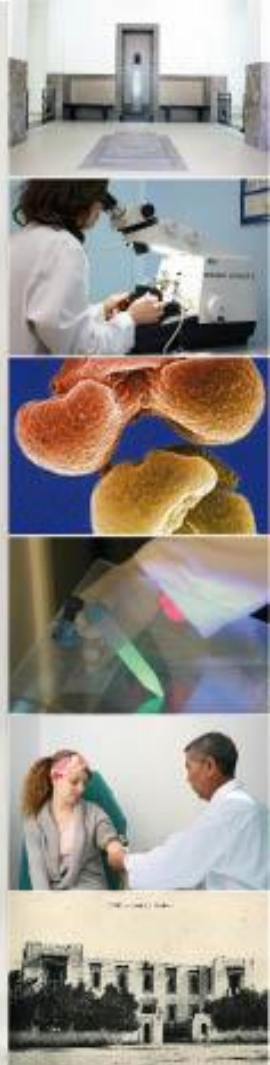




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Institut Pasteur de Tunis

***More than 120 years dedicated to
Public Health***

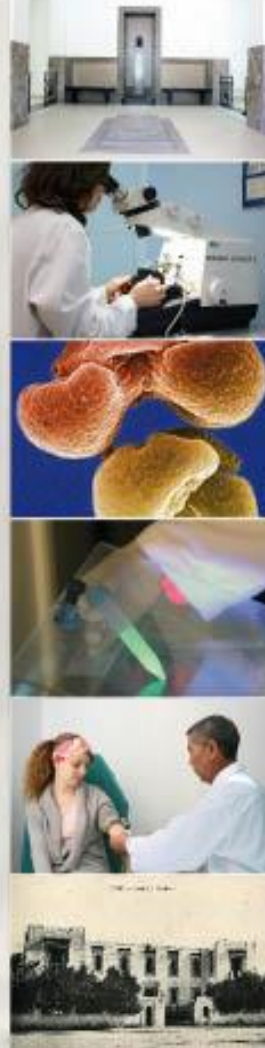




Institut Pasteur de Tunis in 1905



Pioneering discoveries have been made at IPT by Charles Nicolle (Transmission cycles of Typhus, Toxoplasmosis, Visceral leishmaniasis, concept of inapparent infections)



Charles Nicolle, *Institut Pasteur de Tunis* Director 1903-1936, who was awarded the 1928 Nobel Prize in Medicine and Physiology.

Institut Pasteur de Tunis

Mission

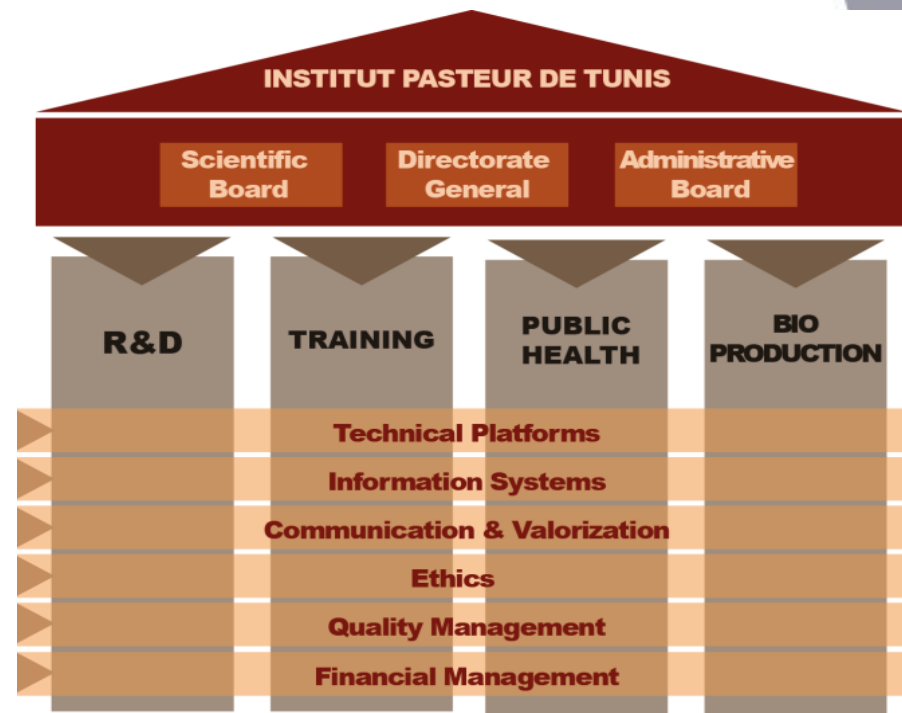
- Biomedical Analysis and Public Health Activities
- Production of therapeutic sera and vaccines
- Research & Development
- Training

Decision bodies (EPS)

- Administrative Council (16 members)
- Scientific Council : DG + 8 elected members from IPT (+4 internationals)

Committees/offices

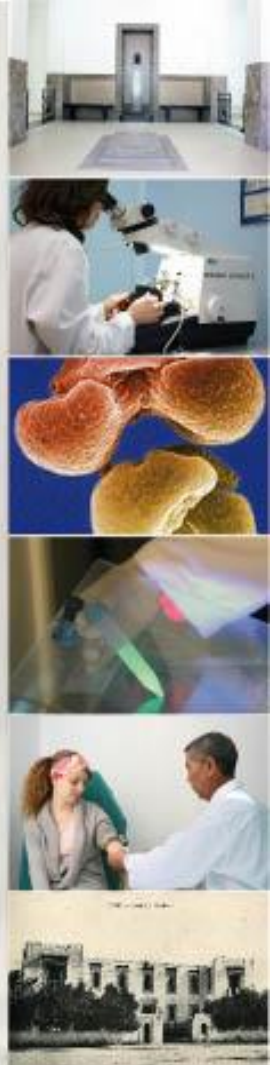
- Ethics Committee
- Communication, valorization and technology transfer
- Health and Safety
- Bioresources
- Quality



Research & development

Field of activities

- **Infectious diseases**
- **Venoms & toxins**
- **Genetic diseases and congenital immune deficiencies**
- **Biotechnology and bioprocesses**
- **Bioinformatics and Mathematical modeling**
- **Clinical Epidemiology and Control (including clinical trials)**





The Institut Pasteur International Network

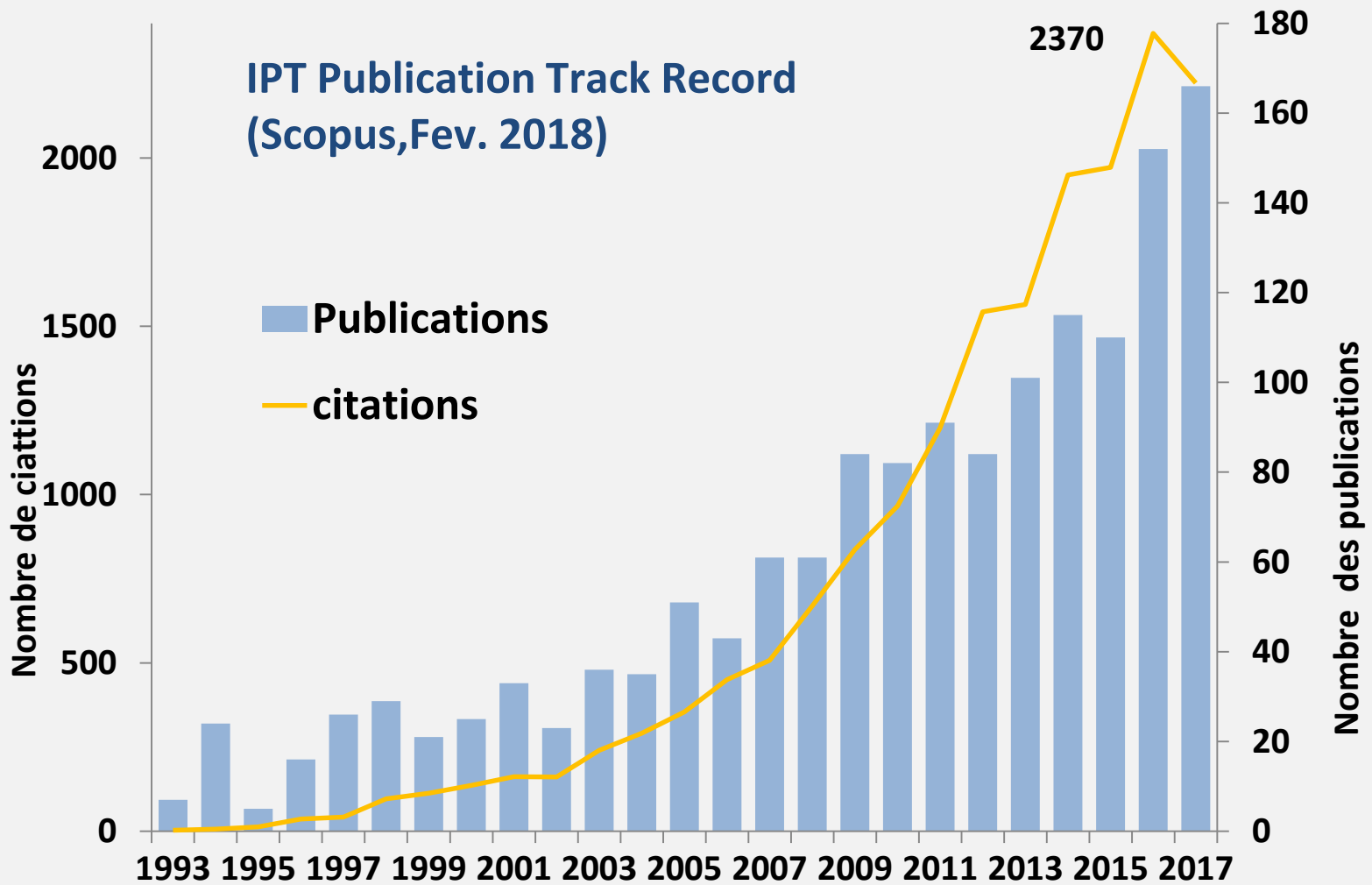


Berlin, 27/01/2016

Institut Pasteur International Network



IPT Publication Track Record (Scopus, Feb. 2018)





Our KTO

- IPT Knowledge Transfer Office aims to foster a conducive environment for the dissemination of IPT research findings
- In these objectives we are assisted by **The Business Development and Technology Transfer Department of Institut Pasteur of Paris**, particularly in **IPR management** (patent filing, patent procedures, links with patent offices).

•Activities:

- ✓ Promote the dissemination of scientific literature
- ✓ Organize workshops and training sessions, produce communication materials, manage relations with the press, provide advice on communication
- ✓ Develop strategies to diversify research income
- ✓ Arrange meetings with companies and partners, and answer Intellectual Property (IP) concerns

Ms Najet Hadhri: Knowledge Manager

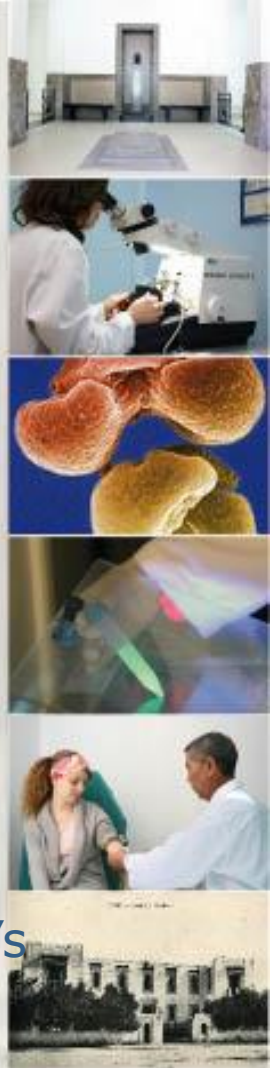
Mr Hichem Ben Hassine : Communication Officer

Mr Oussama Ben Fadhel : Project Manager in Technology Transfer



Clinical Trials

- Treatment of **Cutaneous Leishmaniasis (CL): Study of Phase III** (in Tunisia, IPT) Shows **Antibiotic Cream** Has High Cure Rate, Few Side Effects
- An **international research partnership** from Tunisia, France and the United States (WRAIR). CL is a parasitic disease that causes disfiguring lesions and affects 1.5 million people worldwide annually, including the socio-economically disadvantaged in the developing world, especially children.
- The U.S. Food and Drug Administration (FDA) has designated this new antibiotic cream eligible for fast-track review, given CL's status as a neglected disease. The international research partnership is actively engaged with the FDA to support this review.

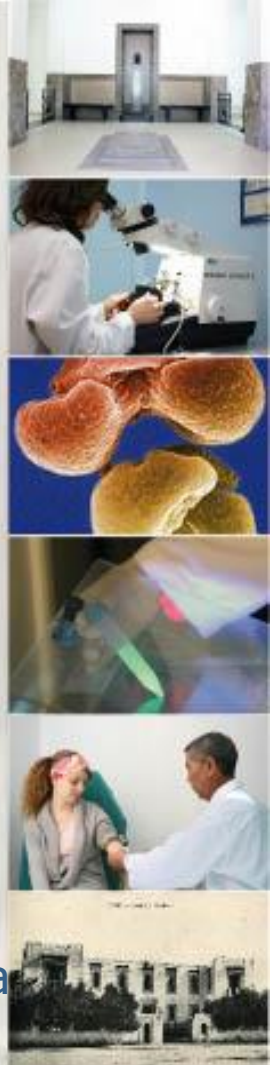




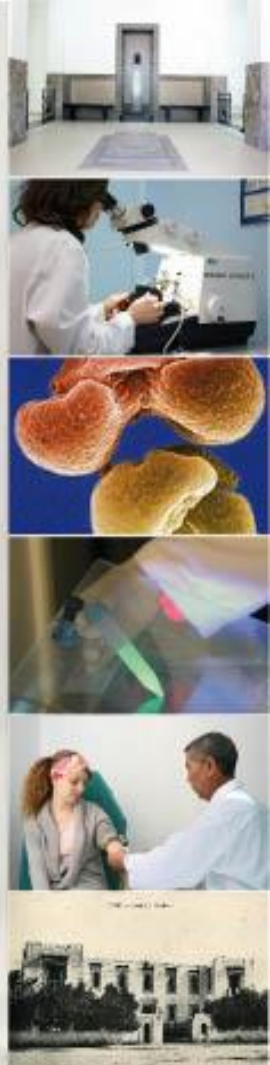
Main Development Programs

Vaccine Development

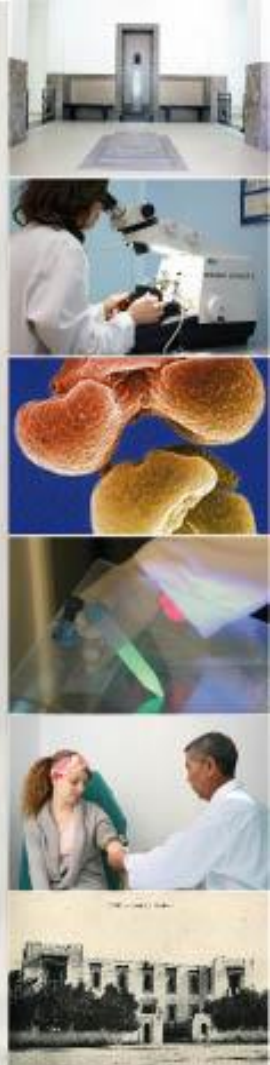
- Development of a **rabies vaccine** for human use at Institut Pasteur de Tunis, Tunisia, in collaboration with international industrial partners, with perspective of production in Tunisia (Under negotiation with industrial partners)
- The National Institutes of Health has agreed to provide researchers from the IPT with the expertise and support to improve the thermostability and the freeze-drying cycle of the rabies vaccine developed at IPT (**WIPO Re Search** connection)
- The BCG vaccine (2 forms): Technology transfer to South Korea (KCDC, GCC) and currently under negotiation with Industrial partner.



- Signature, in 2018, with SATT Lutec of a license agreement on a European patent application entitled "Lebecetin, C-type lectin, as neovascularization inhibitor", December 12, 2016 under No. EP16306661.(Joint invention IPT, IRD)
- In 2018,H2020 twinning project: STRENGTHENING OMICS DATA ANALYSIS CAPACITIES IN PATHOGEN-HOST INTERACTION ; PHINDaccess (Pathogen-Host Interaction Data access) with a Work Package (WP6) dedicated to Technology Transfer : "UNLEASHING IPT'S FULL POTENTIAL FOR AN EFFICIENT TRANSLATIONAL RESEARCH", coordinated by the PM in TT (IPT, C2VT2)→ Deliverable WP6 Task 6.2 An institutional **IP policy**

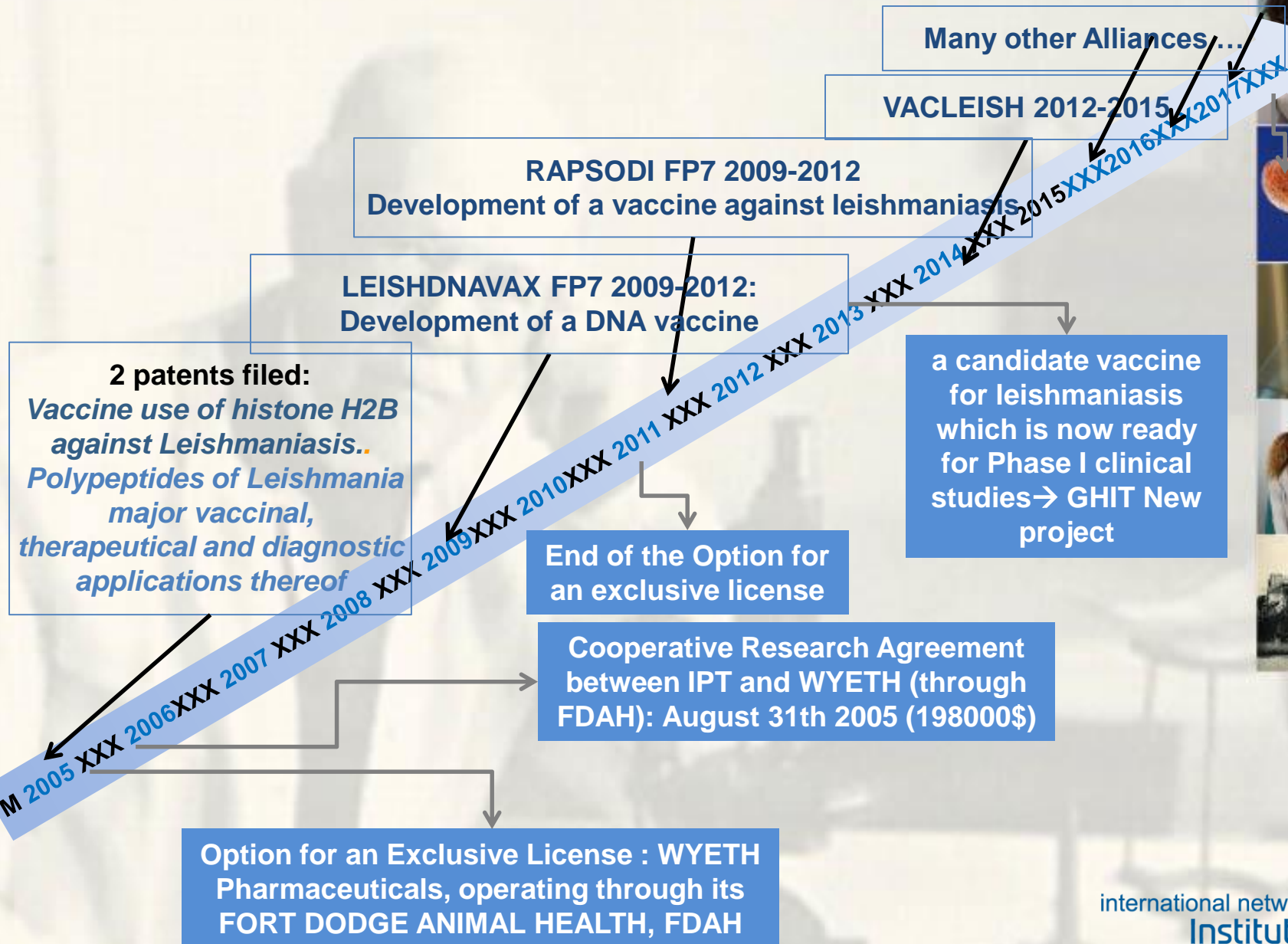
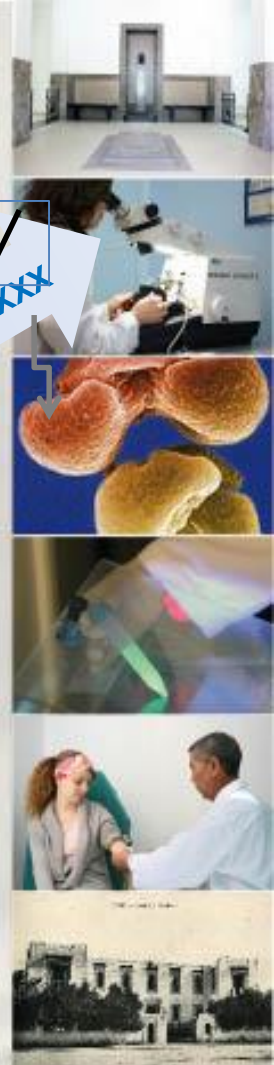


- License on patented technologies : co-ownership on patent
- 1st thing we had to negotiate inventorship in the invention disclosure
- Phd under joint supervision → assignment of rights or sharing ownership?
- Negotiate the coownership agreement on patent
- → TTO should be present all along the process
- Negotiate with TTOs (SATT in France) that had already predefined conditions with Universities since TTOs provide funding to mature technologies.
- → TTOs will handle the negotiation process with Industrials

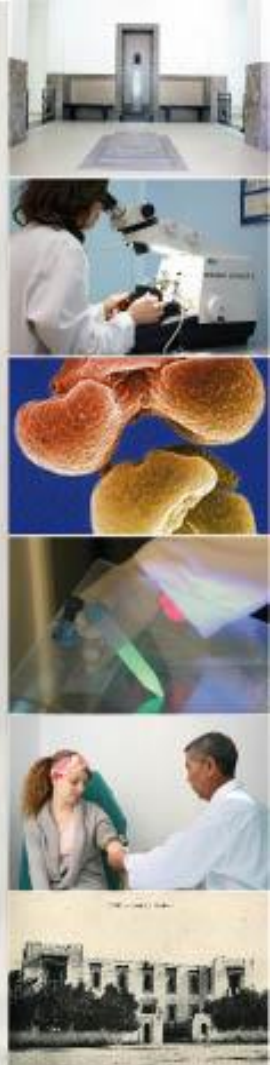




What other activities should we measure?



- Communication is important (Internal & External)
→ Long term relationship based on mutual trust and understanding
- Exclusivity/Nonexclusivity Vs Territory
- Needs to be mutually beneficial
- Ask for Business plan or prepare questions on the market perspective → Essential for the definition of the market / Royalties basis?
- When the payment is due? At the signature of the MTA / Upfront payment/ First batch release / After market approval
- Maintain a database of contacts and keep them current



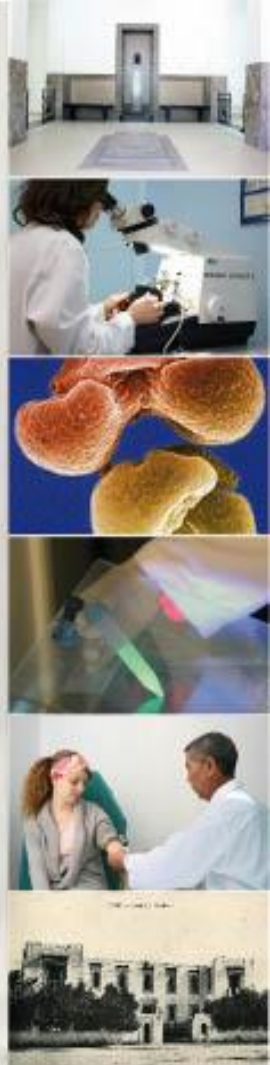
- Training is Key
- Association of University Technology Managers (AUTM, US) or ASTP Proton (EU) → Professional development & Sharing Best Practices
- Get Certified, Get Recognized → Registered Technology Transfer Professionals (RTTP) or Certified Licensing Professional



Any Questions?

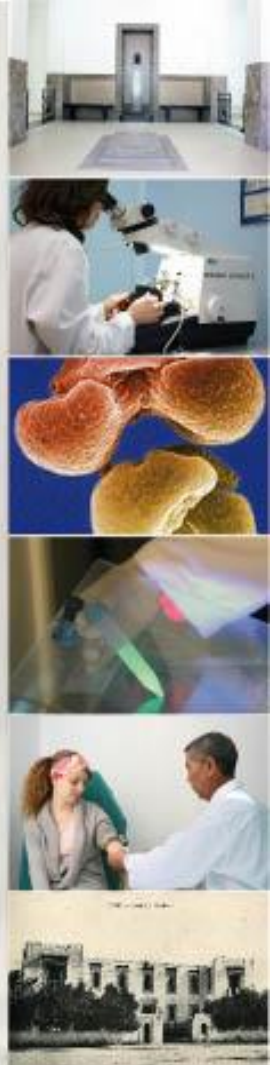
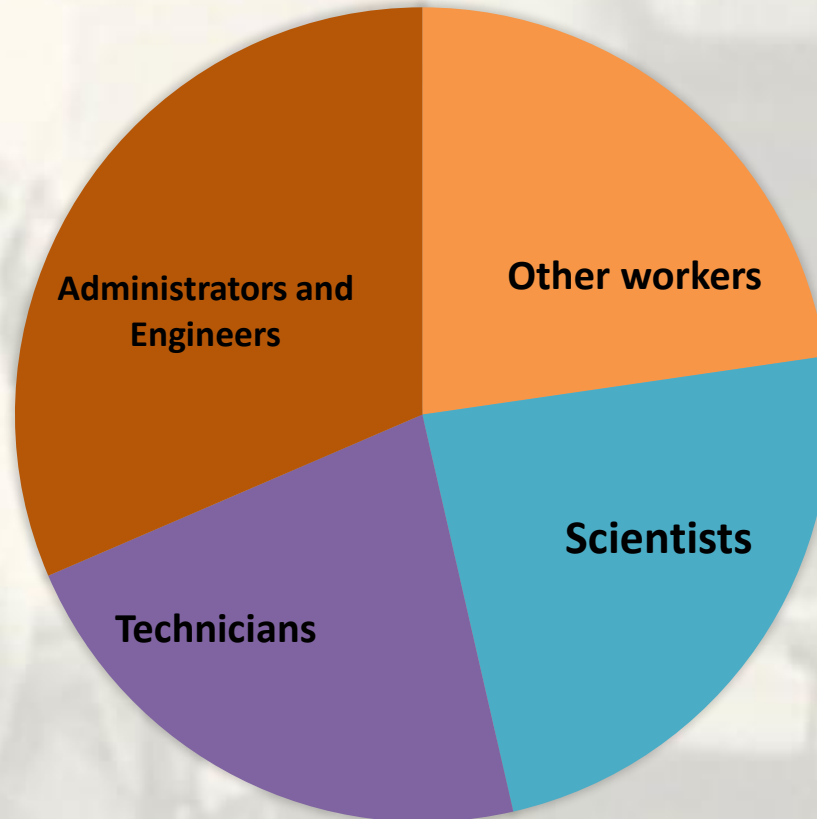
Thank you for your kind attention

Oussama Ben Fadhel
(oussama.benfadhel@pasteur.tn)



Human resources Institut Pasteur de Tunis

- Total: 502
- Scientists: 119





Oussama BEN FADHEL, M.Sc.

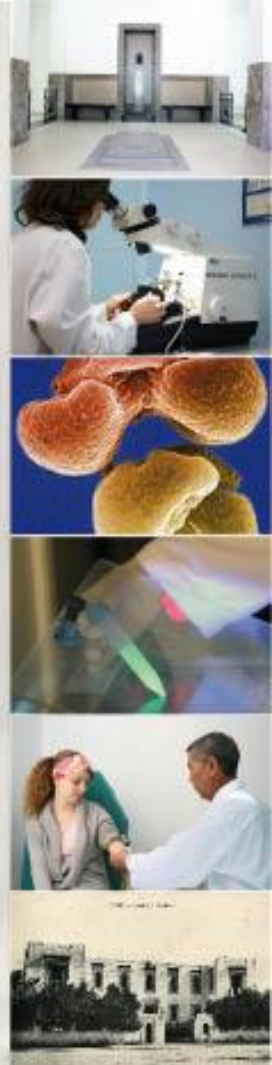
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Institut Pasteur de Tunis (IPT), Tunis



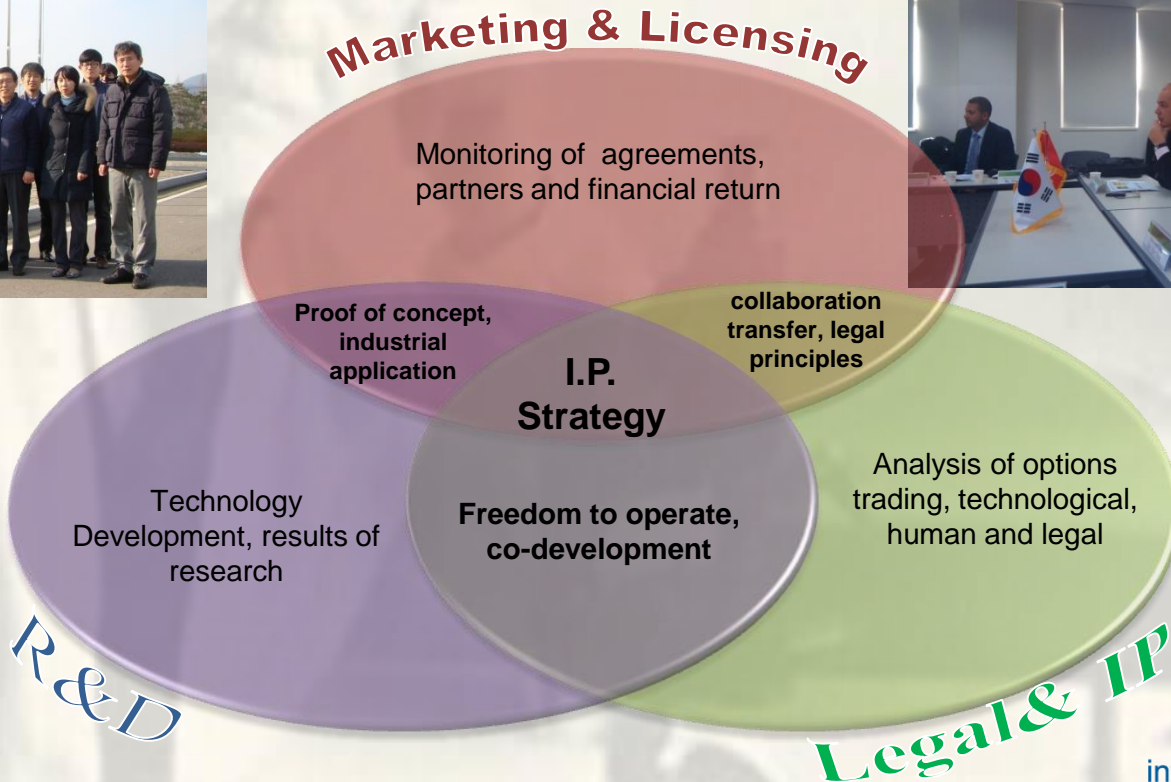
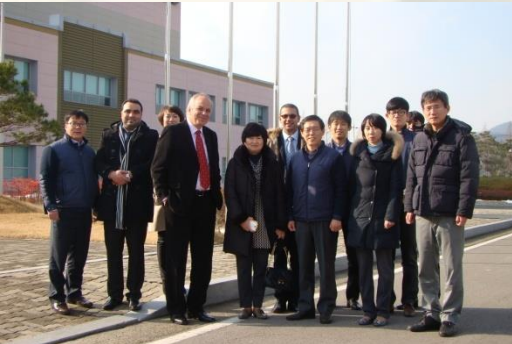
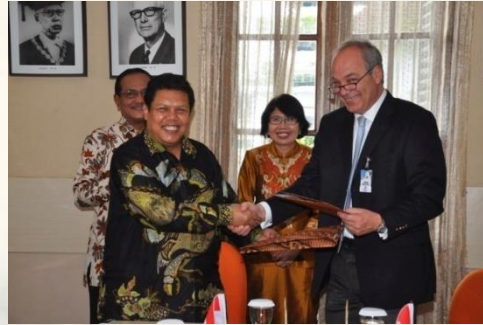
Oussama is the technology transfer manager of the IPT since March 2011. He holds a research Masters of Sciences and Technologies in Integrative Physiology and a professional Masters in Health Law with a specialty in Industrial Property and Health Industries. He is also a PhD candidate, and his focus area is knowledge and technology transfer from public health institutes (biotech related to infectious diseases).

His mission is to promote the commercial development of inventions and industrial partnering (drafting and negotiating agreements, managing patent and intellectual property, preparing marketing materials, and managing relations with industry and supervisory authorities.)

Before joining Institut Pasteur de Tunis, he was a Project Manager in Transfer & Licensing at the Technology Transfer Office at FIST (France Innovation Scientifique et Transfert) of the National Center of Scientific Research in Paris, France. He has been a member of AUTM in 2015-2016.

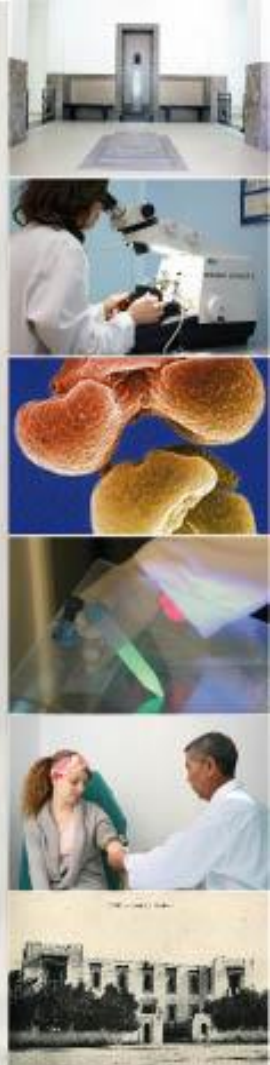


Our process



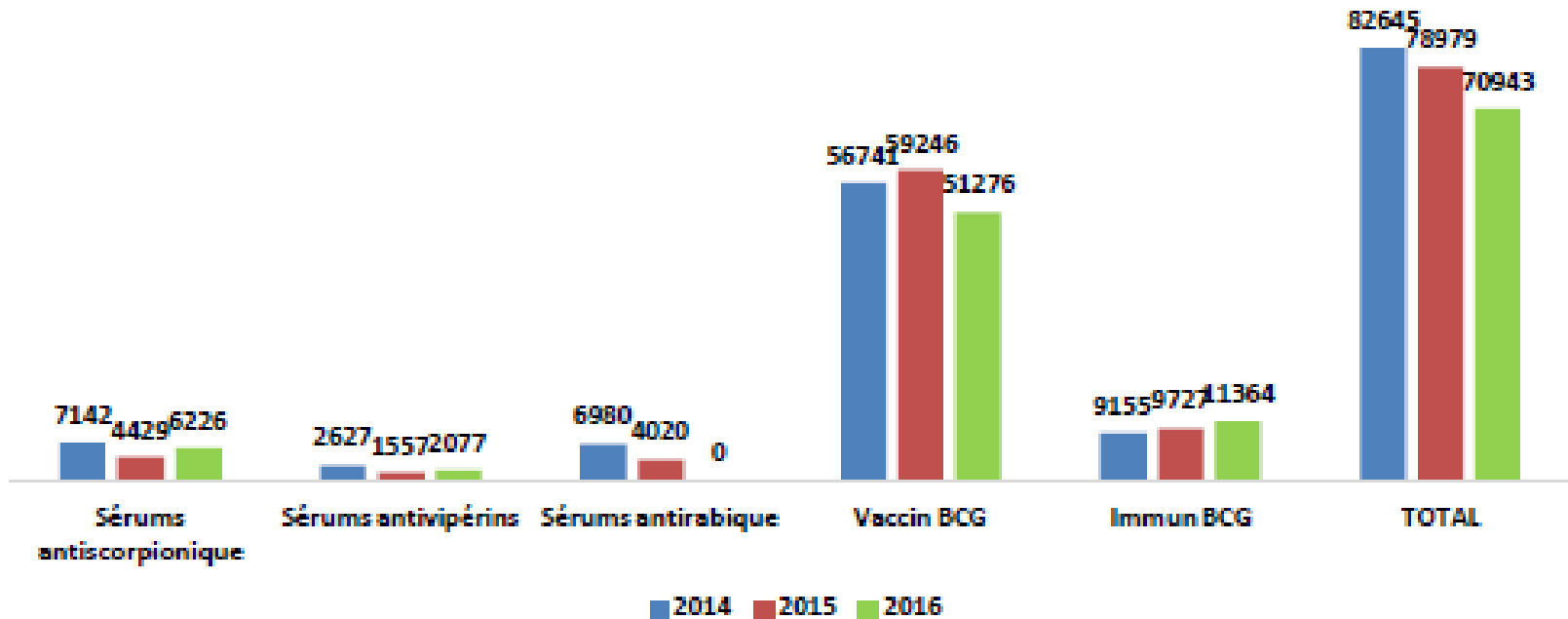
Biomedical Analysis and Public Health activities

- **18 laboratories + 2 services** (35 biologists): Cover the quasi-totality of clinical biology tests. IPT is recognized for the **expertise** of its laboratories in specialized medical biology.
- IPT hosts several national (rabies, poliomyelitis, measles, bacteria, other) or international **reference centers** (for the Eastern Mediterranean Region/WHO: for poliomyelitis and measles, HPV)
- IPT is a center for **vaccination** (for travelers) and a center for **rabies treatment and vaccination** (free).

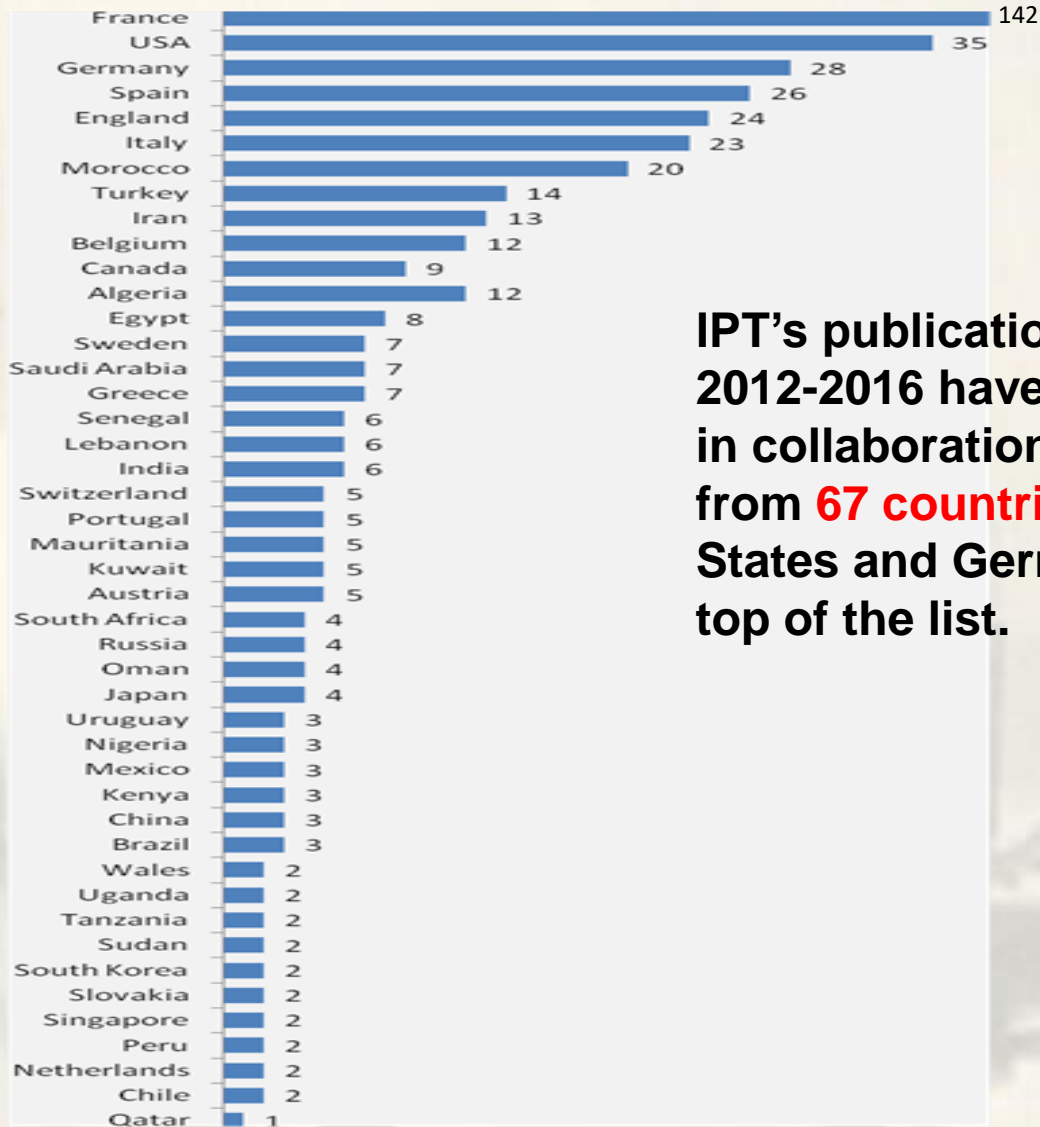


Bioproduction activities

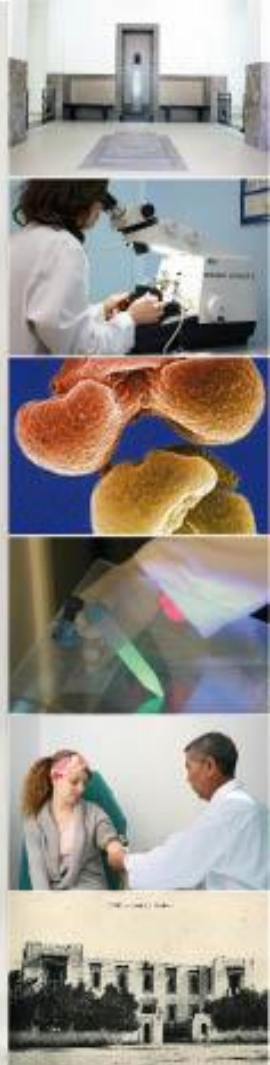
- **BCG vaccine**
 - BCG + solvant
 - Immun BCG
- **Therapeutic sera:**
 - Anti-scorpions : *Androctonus australis*, *Buthus occitanus*
 - Anti-vipera: *Cerastes cerastes*, *Vipera lebetina*



International Partners in IPT publications (Wos; 5 years: 2012-2016: 612 publications)



IPT's publications for the period 2012-2016 have been performed in collaboration with scientists from **67 countries**. France, United States and Germany are at the top of the list.





Funding agencies

ANR (Paris, France)
BIO-RAD (Paris, France)
European Commission (Brussels, Belgium)
Fondation Mérieux (Lyon, France)

Fort Dodge Animal Health
International Atomic Energy Agency
(Vienna, Austria)
Institut Pasteur International Network
(Paris, France)
Joint WHO/EMRO-COMSTech
(Islamabad, Pakistan)
National Institutes of Health (Maryland, USA)
North Atlantic Treaty Organization
(Brussels, Belgium)
The New Partnership for Africa's Development
(Johannesburg, South Africa)
Walter Reed Army Institute Of Research
(USA)
Welcome Trust (London, UK)
WHO/EMRO (Cairo, Egypt)
World Health Organization TDR
(Geneva, Switzerland)

Grant category

R&D
Patent strengthening
R&D
Euro-Mediterranean Public Health
Information System
Vaccine development and validation

R&D capacity building and training

R&D and Public Health Activities (control)

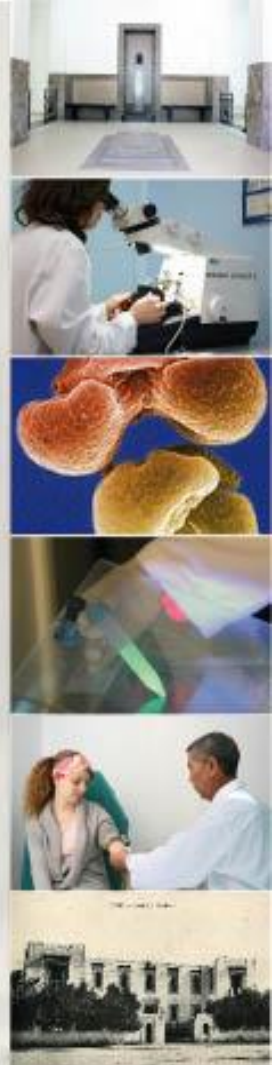
R&D
R&D, clinical research

R&D

R&D

Clinical trials (phase II and phase III)
R&D, training
R&D for control

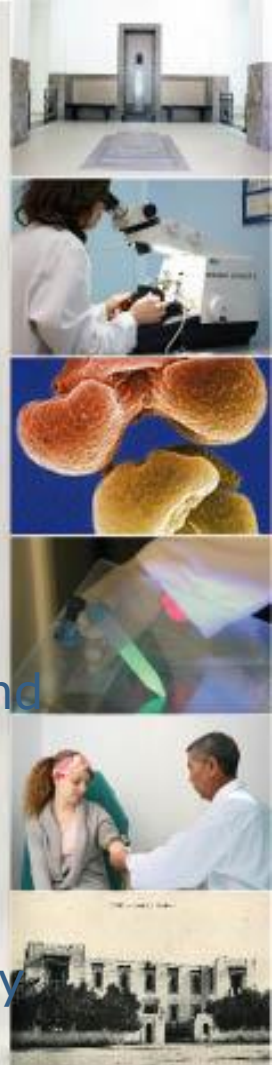
R&D, capacity building, training





WIPO Re:Search support

- 1. WIPO Re:Search** catalyzes the development of medical products for neglected tropical diseases, malaria, and tuberculosis through innovative research partnerships and knowledge sharing.
- 2. Collaborations**
BIO Ventures for Global Health facilitates research collaborations between WIPO Re:Search members, which include biopharmaceutical companies, universities, public and private sector institutes, and non-governmental organizations.
- 3. Database**
Researchers can search in a database of intellectual property assets available for license or collaboration. It includes compounds, data, enabling technologies, know-how etc.





CLDP: The Commercial Law Development Program of the US Department of Commerce



Participation in CLDP events:

- Regional Forum on Establishment of Technology Transfer Offices and Incubators, Istanbul, Turkey, December 3-6, 2013
- Seminar on the Management of Technology Transfer Offices in Tunisia, Istanbul, Turkey, April 8-11, 2013
- Study Tour on Fostering an Innovation and Entrepreneurship Ecosystem in Tunisia Through the Effective Use of TTOs, Faro, Portugal, June 1-5, 2015
- Participation to the AUTM annual meeting in San Diego, February 2016
- One week visiting the Emory University Office of Technology Transfer (OTT) (USA, Atlanta 26 feb-2 march 2018)

