

AUTM Annual Meeting 2011 Las Vegas, NV



« Tech Transfer Across the Pond »

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Tech Transfer Point of View from French University Hospital Center (CHU)



CHU French National Network



- Created in 1958 by Pr R Debré
Agreement between hospital & university

- 27 CHU Networks

• **Threefold mission:**
healthcare, research, education

- Medical staff belonging to both
medical and teaching faculty
- Dual authority:
 - ✓ Ministry of Health
 - ✓ Ministry of Higher Education and Research

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CHU French National Network



- 40 medical schools, 24 pharmacy schools, 16 odontology schools
- 131 rare disease centers
- 17 360 international publications from French CHU
- 1 600 clinical trials in French CHU (793 multicenter)
- 77 300 patients involved in clinical trials sponsored by CHU
 - Patient wins last therapeutical innovations from research with security, quality & ethics
- 2 348 centers involved in clinical research sponsored by CHU
- 5 678 centers involved in clinical research sponsored by companies
- 10 CHU associated to regional competitive clusters

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Challenges to Biomedical Research in University Hospitals



- Birthplace of novel ideas from observations in clinical setting
- Basic biomedical research as part of the mission and vision
- Research hospitals do “R” but not “D”
- CHU & research institutions own their technology invented
- Research discoveries applicable to improve patient care & quality of life; provide overall “Public Benefit”
- Requires translational research and corporate partnerships.....achieved through technology transfer
- New technology knowledge and inventions: natural outcome of basic research




Public hospital funding for the research



National MERRI Envelope (1,8 b€) divided into three parts:

- **A fixed base fee :**
To cover minimum costs for CHU missions: Research, Education, & Innovation (160 M€ for Paris CHU)
- **A modular fee:**
Attributed on relevant indicators results: **Logic of results**
(264 M€ among 191 M€ for publications, 40 for patents)
- **Variable fee:**
Attributed on calls for projects: **Logic of competition**
(77 M€ non comprising projects funding : 34 M€)





Hospital Tech Transfer



Tech Transfer CHU French national network

- All CHU offices of tech transfer or clinical research departments (internal or shared with private universities or their affiliates)
- Working groups (think tank, new regulations)
- Common policies
- Common information documents to industrials and to inventors
- Agreement & contract forms database

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Cultural Challenges to Technology Transfer in France?



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Tools for Tech transfer U.S. vs France



IP Culture



"Congress shall have power . . . To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries"

U.S. Constitution (Art. I, sec. 8)



French people don't publish enough!

"Whatever the point of view chosen, number of patents, publications or Nobel prizes, the figures show that France lost his ranks and falling behind with all the developed nations of Europe and the rest of the world.. "


Luc Teyton, Scripps Research Institute, San Diego



French people don't patent enough!

"It is urgent for France to establish a plan "Innovation and IP" to encourage SMEs to innovate and greater use of IP and to educate SMEs managers to the issue of IP "

French National Society of Patent Attorneys

Within the culture, there was very little use of IP; a high number of disclosures, but patents lost



« Produce knowledge, you wish publish? but you should protect! »

« Protect, then publish, or perish! »





Tools for Tech Transfer U.S. vs France

IP Regulation



Grace period
First to invent



Absolute novelty, no grace to disclosure
First to file



Tools for Tech Transfer U.S. vs France

Regulations



1980: Bayh-Dole Act
The cornerstone of US technology transfer and commercialization



1999: Innovation & Research law, Incubators, spin off from public research, tech transfer
2010: National commitment

Money



Private funds in entrepreneurship, innovation is a promise



Public funds in research, few private funds in company project



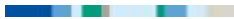
Challenge to Open Collaboration

 10 years ago, exploitation of public research by private industry had a pejorative connotation, even was taboo

Today is exactly the opposite, tech transfer and collaborative research between public and private are encouraged


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Assistance Publique-Hôpitaux de Paris (AP-HP):

Our vision of technology transfer and industrial ventures



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There is a specific hospital innovation, high added value

Healthcare, Teaching and Research

*Tasks of general interest (emergencies, poison control)
Provide access to innovation in larger number of patients*

~~From bench to bedside~~

From bedside...to bedside !

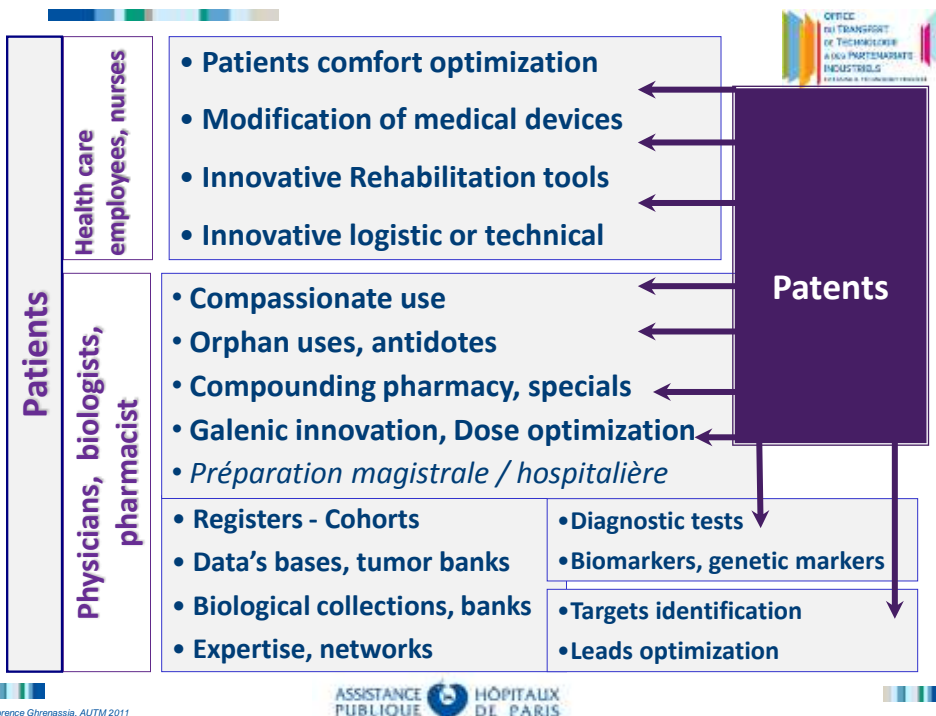
Acquire information from the patient,

Using datas for experimental design

Apply results to patient care

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Hospital: Exclusive partner for clinical research

- Clinical trial validates an innovative use of a product, a new therapeutic strategy
- An innovation can be the result of clinical research (side effects not expected, new indication)
- Sponsor of clinical trial owns the results & datas : useful to file the evaluated product or device (*Raw Data's Transfer*)



Hospital: Exclusive source of biological resources

High value of biological resources for:

- Therapeutic targets
- New diagnostic markers (biological or genetic)
- Markers of treatment response
- Biological samples for validation
- Sources of cells and tissues collections for research tool or therapeutic use

Only qualified biological resources from hospitalized patients for care or clinical research can meet these expectations





Links with biotech and young companies?

Track favored for creation of innovative high-value industrial and commercial start ups



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"Transfer" by entrepreneurship
Allows creation of economic value:
The creation of innovative start-ups



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Young companies creation



- Specific license conditions for project holders
- Integrated or partners incubators & enterprise parks
« Paris Biotech Santé », Agoranov, Biotop Pasteur
- Presentation to various calls for projects funding
(OSEO, ANR, etc. ...)
- Help for finding financial partners and / or alliances
- Help for setting up clinical research projects and
sponsoring by AP-HP

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Products from University Hospital



• Altoprev®	Children's Hospital Boston	Shionogi
• Combivir®	Emory Univ. Medical Center	GSK
• Cyanokit®	AP-HP	Merck
• Diovan®	Brigham & Women's Hosp.	Novartis
• Enbrel®	Massachusetts Gen. Hosp.	Amgen
• Firdapse®	AP-HP	EUSA BIOMARIN
• Fabrazyme®	Mt. Sinai Medical Center	Genzyme
• FluMist®	Univ. of Michigan Med. Ctr.	AstraZeneca
• Flisint®	AP-HP	Sanofi Aventis
• Gardasil®	Georgetown Univ. Med. Ctr.	Merck
• Gleevec®	Dana-Farber Cancer Center	Novartis
• Embospheres®	AP-HP	Biosphere Medical

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Source Joe Fondacaro- Apinnov 2009

Products from University Hospital



• Heptavax-B®	Fox Chase Cancer Ctr.	Merck
• Leustatin®	Brigham Young Univ.	Johnson & Johnson
• Myozyme®	Duke Univ. Med. Ctr.	Genzyme
• Defriprone®	AP-HP	AOPHARMA
• Rotarix®	Cincinnati Children's Hosp.	GSK
• Fomepizole®	AP-HP	OPI Pharma
• Rotateq®	Children's Hosp. Phila.	Merck
• Methadone®	AP-HP	Bouchara Recordati
• Taxol®	Florida State Univ. Med. Ctr.	BMS
• Taxotère®	CNRS	RPR/ Aventis
• Orphacol®	AP-HP	CTRS
• Topamax®	Tufts N.E. Medical Ctr.	Johnson & Johnson

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Source Joe Fondacaro- Apinno 2009



Top 10 AP-HP medical devices

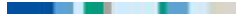


• Blood bag	Macopharma
• Stretcher carrying the body	CIR Médical
• Sorting bins for healthcare - UMAB®	PH2 international
• Expert system temperature monitoring	JRI
• HIV 1&2 tests	Roche /Biorad
• Urethral prosthesis	Coloplast/ PORGES
• Fibrotest® Actitest® (hepatic fibrosis test)	Bioprédicive
• Emergency Check list SAMU - Ez Check®	MP Tronic
• Solution for parenteral nutrition	Fresenius Kabi
• Knee brace	Proteor
• Needle puncture of ascites	Creative Surgical

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Assistance Publique Hôpitaux de Paris AP-HP

First French University Hospital Center



AP-HP

- 37 hospitals in Paris Region
- 89 700 employees
- 6,486 b€ operating budget
- 1 home care unit
- Partnership with 7 universities in Paris Region
- AP-HP first in Europe in sponsored clinical trials; ranks ahead of major industries
- 800 sponsored clinical trials
- 27% of medical research publications in France



OTT&PI : AP-HP Tech Transfer Office



Organization:

- Integrated department
- Team of 12 people (TTO follow-up & assistance)
- 20 external patent attorneys

Accomplishments:

- Total licensing revenues (patents and molecules) 10 M€; total research partnership 4 M€
- For 100 filed patents, 50% licensed in the 2 years
- High power of human access, high power of proof of concept
- 30 startup companies created

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OTT&PI : AP-HP Tech Transfer Office



Activities:

- Patents, know-how, licenses, industrial partners housing
- Start-up companies creation
- Material Transfer Agreement (MTA)
- Research Collaboration Contracts and Partnerships
- Seed funding for research, all calls (clusters, OSEO, ANR,...)
- MEDICEN Cluster
- COVALO: TT corresponding member network in AP-HP
- HTT: national network of Hospital Tech Transfer
- Apinnov, tech transfer day organized once a year; congress and one-to-one business meetings



8th edition: June 16th, 2011 in Paris

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OTT&PI : AP-HP Tech Transfer Office



- 1000 disclosures, up to 500 patent portfolio since 1992
- 400 current international portfolios patents
- 200 licenses and clinical data bases access agreements
- 60 molecules from AP-HP R&D for orphan use or pediatric use
- 120 technologies & know how
- 45 software registered, 29 marks & 17 models registered
- 70 new invention disclosures each year
- 400 research collaborations and industrial partnership/year


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Next Steps in French Technology Transfer: Current Reforms after 10 years of Innovation Law



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Global Tech Transfer Network Reseau CURIE



- Promoting and supporting tech
- 163 public research organizations
- 1000 professionals (TT officers, research contracts, FP7)
- Partnerships with EPO/INPI, ASTP, PROTON, AUTM, SITNET, BTEC
- Staff exchange with USA
- Annual congress gathering 400 professionals
- A unique website gathering the public French tech offers www.F2T.fr




Tech Transfer Between French Public Institutions



New rules from June 2009

Designation of an unique operator between public patent co-owners

Missions:

- Patent management
- Maturation
- Industrial partner research
- Negotiation for licensing or licensing options
- Revenues management



National commitments for innovation



1 billion € invested through a national loan:
« investissements d'avenir »

900 M€, 10 SATT (*Acceleration TT companies*)
50 M€, 5 CVT (*national thematic TT networks*)
50 M€, France Brevet (*IP fund*)

- Enforce autonomy of university & its role on campus
- New organization for technology transfer
- Support technology “proof of concept”; accelerate tech transfer
- Develop high level of professionalism and train staff
- Protect academic researcher enterprise & start up creation
- Create environment to facilitate external partnerships
- Preserve intellectual property rights and protect assets

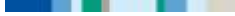
30 years of “Bayh-Dole Act”,

What Do We Learn? *Mark S. Wrighton*



Recommendations of the committee:

- Support strong TTO; not “free agent” ownership of IP
- Develop a vision more focused on “Public Benefit” of technology transfer and not on future revenue
- TTO provide advisory committee guidance to include members of the university & regional economy
- Best practices of patenting and licensing
- Standardized and shorten licensing procedures
- Incorporate recommendations of AUTM (“Nine Points to Consider”)



Providing Innovations with Tools for Success

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Merci beaucoup!

