JOHNS HOPKINS MEDICINE

Academic Industry Partnership (AIP): Managing the relationship

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Disclosure

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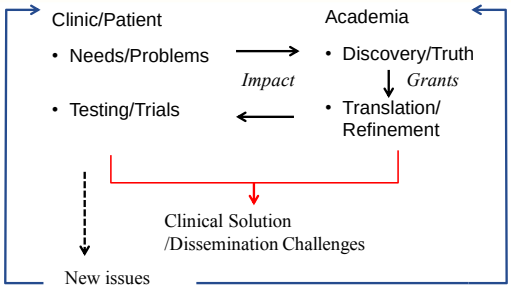
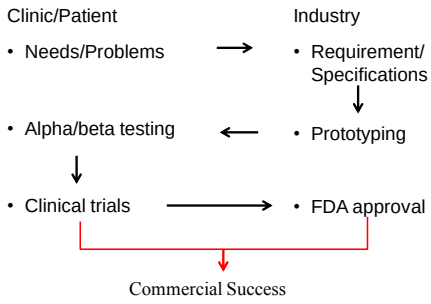
- *Royalty*
  - *Elekta for Cone beam CT; Active Breathing Coordinator*
  - *Xstrahl for Small Animal Radiation Research*
- *Founder of JPLC Associates --- a QA device company*

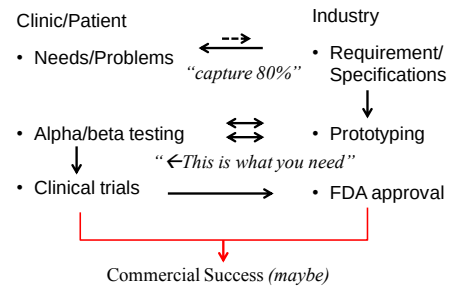
Academia: Clinical Needs & Medical Physics



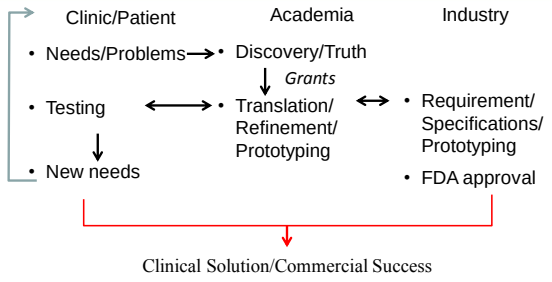
Industry: Clinical Needs & Commercial Products



Industry: Clinical Needs & Commercial Products



A better model: Partnership



Academic Industrial Partnership (AIP): PAR 07-214 → PAR 10-169 → PAR 13-169

- Academic and industrial research partnerships to accelerate the translation of preclinical or clinical in vivo imaging systems and/or methods to solve a targeted cancer problem --- NCI only.
- An inter-disciplinary, multi-institutional research team.
- Support clinical trials.
- Will not support commercial production, or basic research.
- Innovation: coherent translation plan with in-field validation of near commercial quality systems/methods

AIP: A successful translation program

- The pioneering PAR 07-214 funded 37 grants funded: 19 products marketed; 20 clinical trials; 1 CE Mark approval; 24 FDA marketing and investigational approvals; and 79 instances of IP protection.
- 97/542 submissions funded through 2015; results not analyzed for the 27 PAR 10-169 and 20 PAR 13-169 grants
- The AIP procedure is a transformative methodology that provides a new standard for reliable delivery of new capabilities to end users.

Academic and Industrial Collaboration

- Have a clear sense of what and who are we working for
  - Academia → discovery (grants);
  - Industry → successful commercial product
    - Both are necessary to benefit the patient
- The clinic is the laboratory to solve real problems that is available to the industry through academia
- Partnership is not a contract
  - deliverable (of what) is an uncomfortable term;
  - beta testing is a different agreement

How to adapt to changes in the relationship

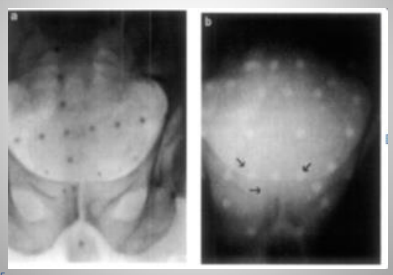
- Have clear expectation of the collaboration
  - IP, personal gain, …. etc
  - First right to refusal,… etc
- Hurdles; Sunshine Act, COI, etc.
- Cannot dictate the direction of the individual partners
  - Industry is looking for knowledge, know-how and profitability
  - Don't get mad if industry chooses a different path
- Academia should look for clinical impact

Secure or renew funding with the industry

- Believe in the impact and vision and stay the course
- Stay ahead to solve the clinical problem at hands
  - A successful clinical solution will likely garner industrial support
- The Academia Industrial Partnership is a great mechanism
  - provides funding to jump-start a project
  - attain the innovation and translation goals of the NCI, the academia and the industry

The Cone-Beam CT story

- Dual Beam Imaging, R01 CA66074, Pre-AIP mechanism
  - The limit of setup accuracy using MV and kV imaging



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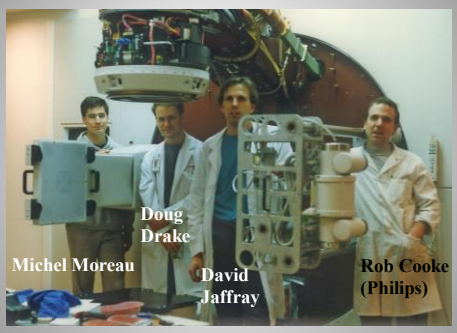
Dual Beam Imaging on Philips SL: 1996

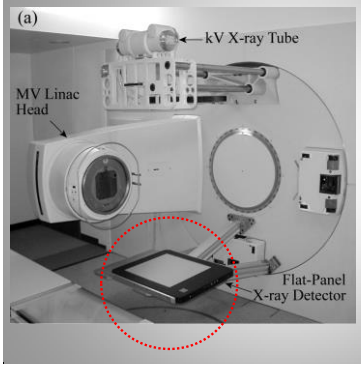
- Not on a product roadmap
- Collaborate with Elekta (then Philips --- Kevin Brown) to mount a kV x-ray source to the drum gantry
- Hire a Philips engineer as consultant

- **April- May, 1997; two weekends; *No Downtime***



A functioning onboard CBCT guidance system

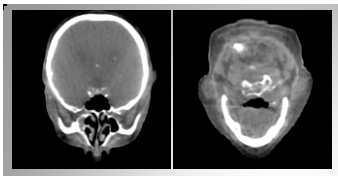
Milestone 2000



- 2000: Elekta facilitated a 41cm x 41cm flat panel imager from EG&G
- Jeff Siewerdsen worked out the performance of the panel
- Formation of the Elekta-Synergy Consortium

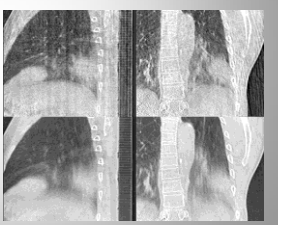
The First Synergy Prototype: Christie 2001

- Synergy consortium (CBCT built on site):
  - Beaumont, Princess Margaret, Christie and NKI
- Clinical workflow developed on site.



William Beaumont Hospital 2002

PMH 2003



NKI 2003

Synergy Product Launch: 2004

Conclusions: Academic Industrial Partnership

- It must be a win-win arrangement
  - Not necessarily a financial gain for academia
- The common goal is to improve healthcare
- Academia is to pursue impact/transformation
- Industry is to produce the next successful and superior product to improve healthcare

- *If you are lucky, you may get both !!!*