JOHNS HOPKINS MEDICINE
RADIATION ONCOLOGY & MOLECULAR RADIATION SCIENCES

Academia-Industrial Partnership An academic perspective

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Disclosure

- *Supported in parts by*
  - R01 CA240811, BRG (PI: Ken Wang)
  - AIP R01/R37 CA230341 (PI: Ken Wang)
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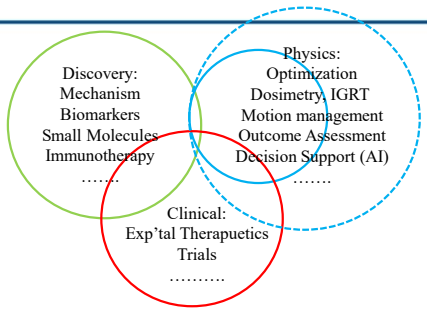
  - *Sponsored Research Agreements: Xstrahl*
- *Royalty*
  - *Elekta for Cone beam CT; Active Breathing Coordinator*
  - *Xstrahl for Small Animal Radiation Research*

AAPM Medical Physics R&D Activities



Funding Opportunities for Medical Physicists

- Public Agencies
  - US Department of Health & Human Services
    - NIH --- NCI, NIBIB, NLM,… ,
    - AHRQ (Agency for Health Care Research and Quality)
  - American Cancer Society (ACS)
  - Congressional directed PCORI
  - DOD, DOE, ….
- Foundations: Damon Runyon Cancer Research, Susan Komen, Terry Fox, ….
- Industries
  - SBIR/STTR
  - Sponsored Research Agreement (SRA)

Nature of Med Phys Research	Funding Mechanism; pre-2007
• Discovery/Hypothesis generating – Response Assessment, Uncertainty Analysis, Outcome Research	• Public Agencies – U01, P01, U54 – R01, R21, …. • Foundations – Damon Runyon;
• Translation (Med Physics) – Decision Support Tools, Instrumentation – Testing and validation	• Public Agencies – SBIR, STTR – ***AIP (2007)*** • Industries (SRA)
• Clinical Translation – Trials	• Foundations: Damon Runyon Cancer Research, Susan Komen, Terry Fox, ….

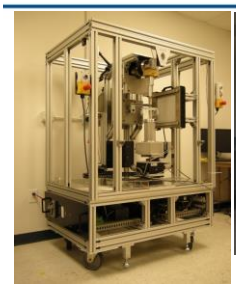
NIH mechanisms for technology translation

- Cone-beam CT for IGRT at WBH: 1995 --- 2005 at WBH
  - R01 → R21/R33, DOD → *Elekta*
- Evolution to large instrumentation (from 2002, …)
  - MR Guidance (Elekta, Canadian Innovation Funds)
  - Small Animal Radiation Research Platform (SARRP) *!?!*
- *PAR 04-023, Bioengineering Research Partnership (BRP)*
  - First crack at improving translations using R01.
  - A multi-disciplinary team (bioengineering, etc) that applies an integrative, systems approach to develop knowledge and/or methods to prevent, detect, diagnose, treat disease or to understand health and behavior.

BRP: SARRP as an early adapter

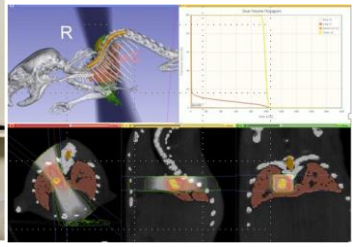
- An image guided small animal radiation research platform (SARRP) is needed to support experiments that mimic modern human treatment methods.
- The integration of expertise in mechanical engineering, x-ray optics and radiation dosimetry physics in a BRP.
  - (1) construction of a gantry system for pre-clinical IGRT
  - (2) development of treatment planning and dosimetry methodologies that parallel that for human treatment
  - (3) develop methods of precise animal setups and irradiation

SARRP BRP (2004 – 2008)
Beaumont, Hopkins, Oakland U, U Toronto



Challenge to disseminate remains

Role of Industry: Dissemination (Xtrahl: 2009 --)



- Dissemination: Workflow, accessories, maintenance
- Continue advancement and development

2007: The advent of Academic Industrial Partnership

- *PAR 07-214: AIP for the Translation of in vivo Imaging Systems for Cancer Investigations (R01 – NCI only 2007)*
  - accelerate the translation of preclinical or clinical in vivo imaging systems or methods to solve a cancer problem
  - **Not** intended to support commercial production, basic research, or clinical studies that lack translation as their primary motivation.
- An inter-disciplinary, multi-institutional research team consisting of both academic and industrial scientists
- Support clinical trials.

AIP: PAR-07-214 Notables

- RO1 scoring criteria:
  - *Significance,* Investigator, *Approach, Innovation,* Environment
  - *Final Impact Score*
- * Innovation grows in robustness by delivering functionality of a new capability to end users
  - coherent translation plan with in-field validation of near commercial quality systems/methods
  - guidelines modified to include likelihood to deliver to end-users
- * Novelty of the proposed research methods is of secondary importance
- * *AIP provides the important link of innovation and needs between research, clinical translation and industries*

PAR 07-214 A successful translation program

- The pioneering PAR 07-214 funded 37 grants:
  - 9 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;
  - Update needed for the 27 PAR 10-169 and 20 PAR 13-169 grants

AIP: PAR
Program Announcement with Special Review Criteria

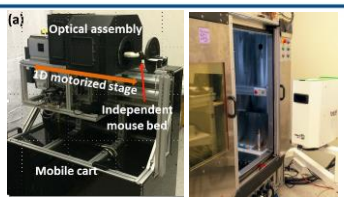
- *Translation of in vivo Imaging Systems for Cancer Investigations (R01)*
  - PAR-07-214.html (new); PAR-10-169; PAR-13-169 (reissue)
  - NCI; *ended*
- *Translation of Technologies for Cancer Diagnosis and Treatment (R01)*
  - PAR-15-075.html (new); PAR-18-530.html (reissue)
  - NCI, NIBIB → NCI, NIBIB, NIDCR,
- *Translate and Validate in vivo Cancer Imaging Systems (R01)*
  - PAR-17-093.html (new); PAR-18-009.html (reissue)
  - NCI, NIDDK, → NCI, NIBIB, NIDCR, NIDDK

PAR 10-169: from BRP to AIP
X-ray/optical tomography for preclinical rad res (2011)

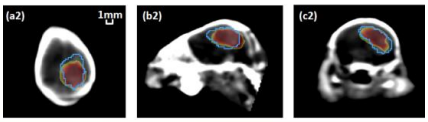
- We identify (hypothesize) that a most suitable solution for soft tissue target localization is to incorporate molecular-optical on board the SARRP. We submit our proposal in response to PAR-10-169 for in vivo imaging research.
- Our specific aims for the *3-year (??)* research period are to:
  1. Design and construct an integrated CBCT-BLT system on-board the SARRP to guide focal irradiation; and
  2. Validate at three academic partner institutions the accuracy of BLT: Hopkins, Penn, UVA (--- emphasizing innovation)
  - Gulmay (Xstrahl) is the AIP

AIP translation: Xstrahl MuriGlo
Successful Continuation: PAR 10-169 to PAR 18-009

Hopkins In-house System



Xstrahl's Swing Door System



PAR 10-169:
Integrated 3D X-Ray/ultrasound for IGRT (2011)

- We hypothesize that integrated on-board 3D ultrasound and CBCT imaging provides a superior IGRT solution (alternative to MRI).
  - Design, construct and optimize workflow of the system
  - *Validate at two academic institutions (Hopkins and Cleveland Clinic)*
    - *Elekta as the AIP:* ***Continuation - dissemination unsuccessful***

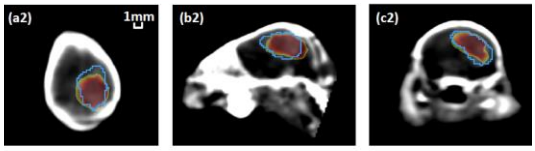
AIP preparation: Note new review issues

- *In addition to Innovation of end-user validation:*
- Governance and organization structure outline:
  - Overall organization, technical, pre-clinical and clinical responsibilities, ….. shared leadership, administration, conflict resolution, etc.
- Provide timeline and performance (error and statistical) metrics.
- Readiness for translation; provide preliminary data that support the study plan, feasibility, and approach to validation.
- A single institution or clinic is a *valid* end-user

Conclusions: AIP mechanism

- AIP's translation theme is a well-suited and effective mechanism for medical physics research
  - take a programmatic (vs a project) approach
- Other PI's: R Berbeco, A Sawant, …. many imaging colleagues
- Review the details of the FOA and PAR
  - PAR-18-009; PAR-18-530
- AIP provides important support for research translation
  - *It helps but does not guarantee dissemination !!!*

PAR-10-169 to PAR-18-009: Successful Continuation



Coronal Sagittal Transverse

- R01/R37 CA230341 (Ken Wang): X-ray/optical tomographic guidance and assessment system for pre-clinical radiation research
  - Design and construct a new advanced BLT/FT system to guide irradiation on-board the SARRP and for off-line treatment assessment.
  - 5 year research period, Hopkins is the end-user