

Topics 1 and 2:

NCI, Cancer Imaging Program & Radiation Research Program

To bring bioengineering funding opportunity announcements for everyone, not just small businesses, we formed the Bioengineering Consortium at NIH.

- Developed Three series of announcements, still ongoing.
 - For late stage, middle stage, and early stage developments.
- <https://grants.nih.gov/grants/guide/pa-files/PAR-19-156.html>
Bioengineering Research Partnerships (AIP)(U01 Clinical Trial Not Allowed), also PAR-19-157 (U01 Clinical Trial Required)
 - Comments: These were developed for advanced stage technology developments. Cooperative Agreement means a government selected scientist will participate. The Academic-Industrial Partnership is recommended as better for translations.

Topic 1, K. Farahani; Topic 2: C. Obcemia

NCI's Cancer Imaging & Radiation Research Programs

- <https://dctd.cancer.gov/FundingPartnerships/PAsRFAs.htm>
- Navigate to *Cancer Imaging Program* or imaging.cancer.gov then research funding.
 - <https://grants.nih.gov/grants/guide/pa-files/PAR-19-158.html>
Bioengineering Research Grants (BRG) (R01 Clin trial not allowed). see companion PAR-19-159, Clin trial required.
 - <https://grants.nih.gov/grants/guide/pa-files/PAR-19-149.html>
Exploratory/Developmental Bioengineering Research Grants (EBRG) (R21 Clinical Trial Not Allowed) also PAR-19-150 (R21 Clinical Trial Optional)

Topic 1, K. Farahani; Topic 2: C. Obcemia

NCI's Cancer Imaging & Radiation Research Programs

For early stage validations:

- <https://grants.nih.gov/grants/guide/pa-files/par-18-560.html> NCI's Investigator-Initiated Early Phase Clinical Trials for Cancer Treatment and Diagnosis (R01 Clinical Trial Required)

For early stage validations:

- Academic-industrial partnerships for translation of technology developments: Deferred to Topic 3, next talk.

Two NCI-issued AIP Announcements are active

PAR-18-009: *Academic-Industrial Partnerships to Translate and Validate in vivo Cancer Imaging Systems* (R01-Clinical trials optional).

- Standard R01 receipt dates.
- Renewal in process.

PAR-18-530: *Academic-Industrial Partnerships for Translation of Technologies for Diagnosis and Treatment* (R01-Clinical trials optional).

Four NIH Institutes sponsor AIPs

- NCI-National Cancer Institute—Lead Sponsor
- NIDCR-National Institute on Dental and Craniofacial Research
- NIDDK-National Institute of Diabetes and Digestive and Kidney Diseases
- NIBIB-National Institute of Biomedical Imaging and Bioengineering

- Tip:** Where you see *Cancer*, substitute *Disease of Interest*.
- Tip:** Ask the institute’s scientific contact:
- Does my project fit? Do you impose mandatory budget reductions? How many years may we budget, 4 or 5?

AIP success was by design
Strategic Alliances Emerge as a Strategy

Strategic alliances help translations succeed; they do better with academic and industrial partners—which AIP requires.

Background: This realization emerged gradually:

- When Small Business Innovation Research (SBIR) grants came to NIH in FY1984, they allowed academic participation.
- When Small Business Technology Transfer Research (STTR) started FY1993, they required academic participation.
- FY1998: NIH Bioengineering Consortium (BECON) added an R21 + two R01s to cover early, middle and late-stage technology developments—anyone is eligible to apply.
 - The Bioengineering Research Partnership (BRP) R01 required partners but did not say what kind.

AIP success—by design

Lessons from *Novel Technologies for in vivo Imaging*

Bioengineering had a review problem: fundable scores were about half as frequent as for hypothesis-driven R01s.

- Engineering innovations were seen as ‘high risk, high gain’—High risk up front and maybe high gain later.

To reduce up-front risk, *Novel Technologies* applications required two phases of funding—with a short pause to decide transition.

Lessons learned:

- 35 of 37 transitioned: Not so risky after all.
- Objective performance targets expedited transition decisions.
- Transition decisions stopped momentum, created job anxiety.

For AIPs we decided to skip phasing and go for 5 year R01s.

AIP success—by design

A more realistic definition of *Innovation*

AIP defines Innovation as **likelihood to deliver a new capability to end users**. Deliberately broad. Suits all projects. Offsets two reviewer proclivities:

- Many reviewers see innovation as risky. If much time passes to work up next steps, ‘It’s no longer new!’ ‘Can’t give a good score.’

We took an **optimistic view**:

- Engineers and scientists: good at workarounds to manage risk.
- Showing a new idea is feasible makes it more tangible,
 - Working prototype adds prospects for utility,
 - Same for next steps : functionality, reliability, operability, lower costs, validation, manufacturability. Altogether,
- **Innovation peaks upon delivery of a new capability to end users.**

AIP put it all together

A funding opportunity optimized for translations

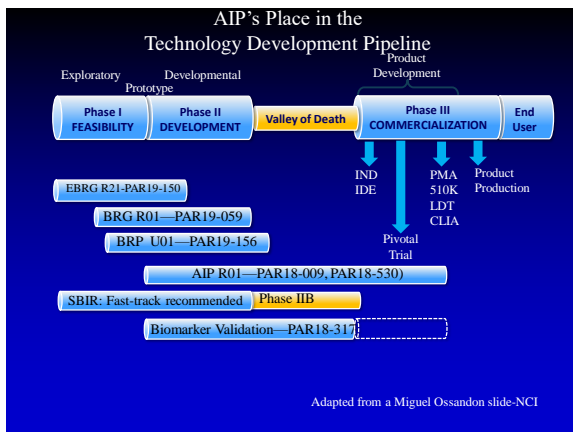
PAR-07-214 funded its first grants in FY2008. The series continues.

- All are reviewed by Special Emphasis Panels (SEP)—with *ad hoc* reviewers.

Tip: Read the review criteria, a list of questions reviewers are expected to consider. Make sure your application has answers.

Closing Slides cover:

- **Where AIPs fit with bioengineering** funding opportunities.
 - AIPs serve translation-ready outcomes from bioengineering grants.
- Tips on preparing an application.
- Selected PAR-10-169 results: O’Dorisio, Wiskin, and Lin projects.
- Slides added to cover Session Topics 1 & 2: Cancer Imaging Program and Radiation Research Program Funding Opportunities



Tips on preparing an AIP Application Request Guidance Documents

- Read the PAR: especially Purpose, Research Plan, Review Criteria.
- State a problem, significance, solution (or mitigation)—up front, 3 sentences max.
- What new capability do you intend to deliver to end users?
- Describe each partner's role: show academic-industrial bi-directional flow.
- Who are your intended users? Researchers? Clinicians?
- Non-clinical? Clinical? Care delivery? Disparity reduction? High, middle, or low resource setting? Underserved population?
- Include preliminary data to show your approach works and ready to translate.
- Innovation: Is it likely to deliver a new capability to end-users?
- Budget limits—check with the Institute: 4 or 5 years? Direct cost policy cuts?
 - Co-funding is not required: each partner may draw funds.
- Mention or quote review elements specific to AIP, which differ from 'standard R01s' to remind *ad hoc* reviewers.

Recent AIP Success—O'Dorisio

Image-guided diagnosis and therapy of neuroendocrine tumors

CA167632, M Sue O'Dorisio and Yusuf Menda –
University of Iowa, Eckert-Zeigler Eurotope GmbH, Molecular Insight Pharmaceuticals, Iowa City Veterans Administration Medical Center

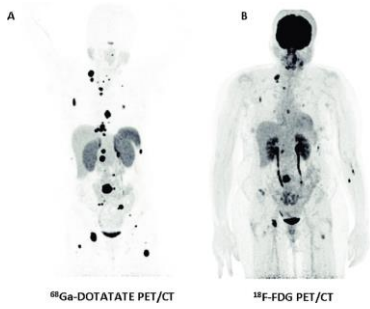
Two products:

- On site automated GMP synthesis by cassette: neuroendocrine-tumor-targeted PET imaging agents; targeted therapeutics.
- ¹⁷⁷Lu-DOTATATE Peptide Receptor Radionuclide Therapy (PRRT).

They changed the standard of care for PET neuroendocrine tumor diagnosis, therapy and treatment monitoring

- SNMMI issued *Appropriate Use and Cost (AUC) Factsheet*—to guide clinicians on appropriate use these new tools.

Ga-68-DOTATATE PET/CT



NATIONAL CANCER INSTITUTE

19

Recent AIP Success—Wiskin

Quantitative 3D ultrasound breast scanner for cancer detection and diagnosis

CA138536, Steven Abbott Johnson (d), James Wiskin – QT Ultrasound, LLC; University of Texas Southwestern

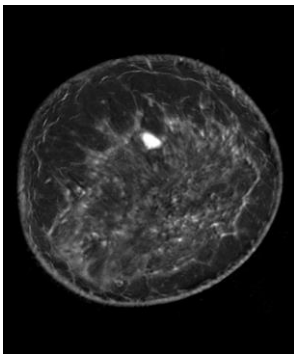
One Product: quantitative ultrasound-based CT

- Ultrasound Transmission Wave breast scanner.
- FDA Breakthrough Device designation.

NATIONAL CANCER INSTITUTE

20

QT Ultrasound LLC: Breast Ultrasound Tomography Native contrast, 100 micron isotropic resolution



NATIONAL CANCER INSTITUTE

21

Recent AIP Success—Lin

See, Reach, Treat Tumor-Optimized Transarterial Chemoembolization Drug Delivery

CA160771, Nikhil Bhagat (ESI), Jean-Francois Geschwind; MingDe Lin
Johns Hopkins University; Philips Research North America

Three products marketed:

- AlluraClarity, EmboGuide, and qEASL* to 'See, reach, and treat' liver cancers, and quantitatively track therapeutic response.

*qEASL: Tracks therapeutic response by quantitative changes in image enhancement, per European Association for the Study of the Liver.

Philips EmboGuide

