



CAIRIBU CONNECTIONS DISCUSSION

RADIATION CYSTITIS RESEARCH ACROSS THE TRANSLATIONAL SPECTRUM

SUMMARY 4/20/2026 CAIRIBU CONNECTIONS

Goal: Reviewing academic to biotech, bench to bedside research to address radiation cystitis.

CAIRIBU CONNECTIONS

FEAT: MICHAEL CHANCELLOR, MD

**RADIATION CYSTITIS RESEARCH ACROSS
THE TRANSLATIONAL SPECTRUM**

4/20/26 [3-4PM ET]



Seven Milestones of the Translational Journey in Radiation Cystitis

1. Identifying and Addressing an Unmet Need

- Hemorrhagic cystitis is serious, life-threatening bladder damage from pelvic radiation therapy and/or bladder-toxic chemotherapy. It has no approved drug therapy and a four percent mortality rate. It affects 5-10% of pelvic radiation patients
- Dr. Chancellor explained that lack of approved therapy and orphan patient population (<200,000 patients in US impacted) meant he could pursue the **orphan drug designation regulatory pathway**.

2. Developing Clinically Relevant Preclinical Models

- Based on his experience, **Dr. Chancellor suggested investing in animal model development early** because FDA requires clinically relevant animal models for Investigational New Drug (IND) submission.
- At Beaumont/Corewell, the Small Animal Radiation Research Platform (SARRP) modeled human radiation cystitis. External beam radiation precisely targeted bladder while sparing surrounding structures, its clinical relevance was demonstrated through progressive hematuria, reduced capacity, and histologic changes, and standardized protocol enabled reliable efficacy testing across studies.
- Teamwork was key during this stage

3. Liposomal Tacrolimus Innovation

- He explained his choice of tacrolimus for development. From a scientific standpoint, tacrolimus:
 - Is a potent immunosuppressant with anti-inflammatory properties
 - Can be delivered intravesically
 - Prolongs local tissue retention
 - Has minimal systemic absorption
- Dr. Chancellor advised that strong intellectual property is instrumental for startup viability and investor interest, so **investigators should work with their technology transfer offices early**, have a patent strategy prior to publication, and consider both composition of matter AND method of use patents
- GMP (Good Manufacturing Practices)-grade manufacturing for CTs and regulatory approval are a must. GMP compliance attracts industry partners and investors.
- While in-house capability can accelerate iteration, Dr. Chancellor encouraged findings partners who can speed scale-up.
- He advised simple manufacturing using inherently safe materials, low cost of goods, and scalable unit operations.

4. Crossing the Valley of Death

- **Dr. Chancellor introduced the concept of the “valley of death.”** These are the challenges faced when transferring knowledge from applied research to launching a biomedical product and collaborating between academia and industry.
- He emphasized multiple valleys of death, from pre-clinical to clinical trials (CTs) and FDA approval.

- To move from academic discovery to patient deployment, enlist regulatory experts and experienced management and develop manufacturing partnerships or in-house manufacturing (GMP facility).
- University spinouts require clear IP licensing agreements.
- Engage FDA earlier and seek accelerated pathways.

5. SBIR Funding: Higher Than R01, Different Rules

- **Can bring in \$2-3M+ in non-dilutive funding**
- Can bring in funding for academic and company sides.
- **Must be a legitimate small business** – not just a university spinout on paper – with operational infrastructure – NOT a shell entity, and PI must be employed by the company (>51% of the time).
- SBIR is preferred over STTR by NIH because of reviewers' experiences with start-ups

6. FDA Pathways:

Orphan Drug Designation Pathway

- For diseases affecting <200,000 patients in US. Radiation cystitis qualified for this based on prevalence data and lack of approved therapies.
- Dr. Chancellor said this designation gives you 7 years market exclusivity, 25% tax credit on CTs, reduced FDA filing fees, and enhanced FDA guidance.
- **He advised to pursue this early if your disease meets the criteria** – it can accelerate your timeline via “Breakthrough” or “Fast Track” designations.

505(b)(2) Pathway

- This hybrid “new drug application” pathway references FDA’s prior findings for approved drugs.
- It saves time and money by referencing existing safety data (no need to prove safety again), reducing chemistry, manufacturing, and controls requirements (CMCs), allowing you to focus clinical studies on efficacy in new indications.

7. Patient Advocacy and Stakeholders

- Dr. Chancellor advised to **partner early with patient advocacy organizations, not just for recruitment**. These organizations can help you build patient registries, he explained, allowing you to access natural history data, treatment patterns, and outcomes tracking. The registry strengthens regulatory submissions.
- Other advice – Engage FDA early through pre-IND meetings, develop key opinion leaders network for CT sites, and incorporate patient-reported outcomes.

Michael Chancellor, MD, is a highly experienced translational scientist with a stellar track record spanning over 25 years. As a distinguished former Professor at the University of Pittsburgh he has a proven track record of developing groundbreaking technology that has been licensed to Cook Medical, leading to the establishment of Cook MyoSite - a cutting-edge clinical-phase cellular therapy company. With a state-of-the-art GMP production center and a workforce of approximately 200 employees based in Pittsburgh, Cook MyoSite is at the forefront of the industry. His expertise spans across multiple disciplines, including Medical Devices, Oncology, Molecular Biology, Tissue Engineering, and Biotechnology.
