Initial Report of a Randomized Trial Comparing Conventional- vs Conventional plus Fluciclovine (^{18}F) PET/CT Imaging-Guided Post-Prostatectomy Radiotherapy for Prostate Cancer

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Disclosures

Funding Source: NIH – RO1 CA169188 (PI's: Dr. Ashesh B. Jani / Dr. David Schuster)

- Dr. Ashesh B. Jani:
  - Employee: Emory University / The Emory Clinic
  - Advisory Board: Blue Earth Diagnostics, Ltd. (last in 3/2018)
- Dr. Mark Goodman:
  - Royalties: Nihon MediPhysics Co, Ltd.
- Dr. David Schuster:
  - Consultant: Syncona; AIM Specialty Health; Global Medical Solutions Taiwan; Progenics Pharmaceuticals, Inc.
  - Research Grants: Blue Earth Diagnostics, Ltd; Nihon MediPhysics Co, Ltd.; Telix Pharmaceuticals (US) Inc.; Advanced Accelerator Applications; FUJIFILM Pharmaceuticals U.S.A., Inc; Amgen
- Emory University:
  - Blue Earth Diagnostics, Ltd. (Cassette Arrangement)

Background

- The decision to offer radiation after prostatectomy for patients with recurrent prostate cancer is complex
  - High failure rates
  - More accurate radiation therapy decisions and treatment planning needed
  - Limitations of conventional imaging

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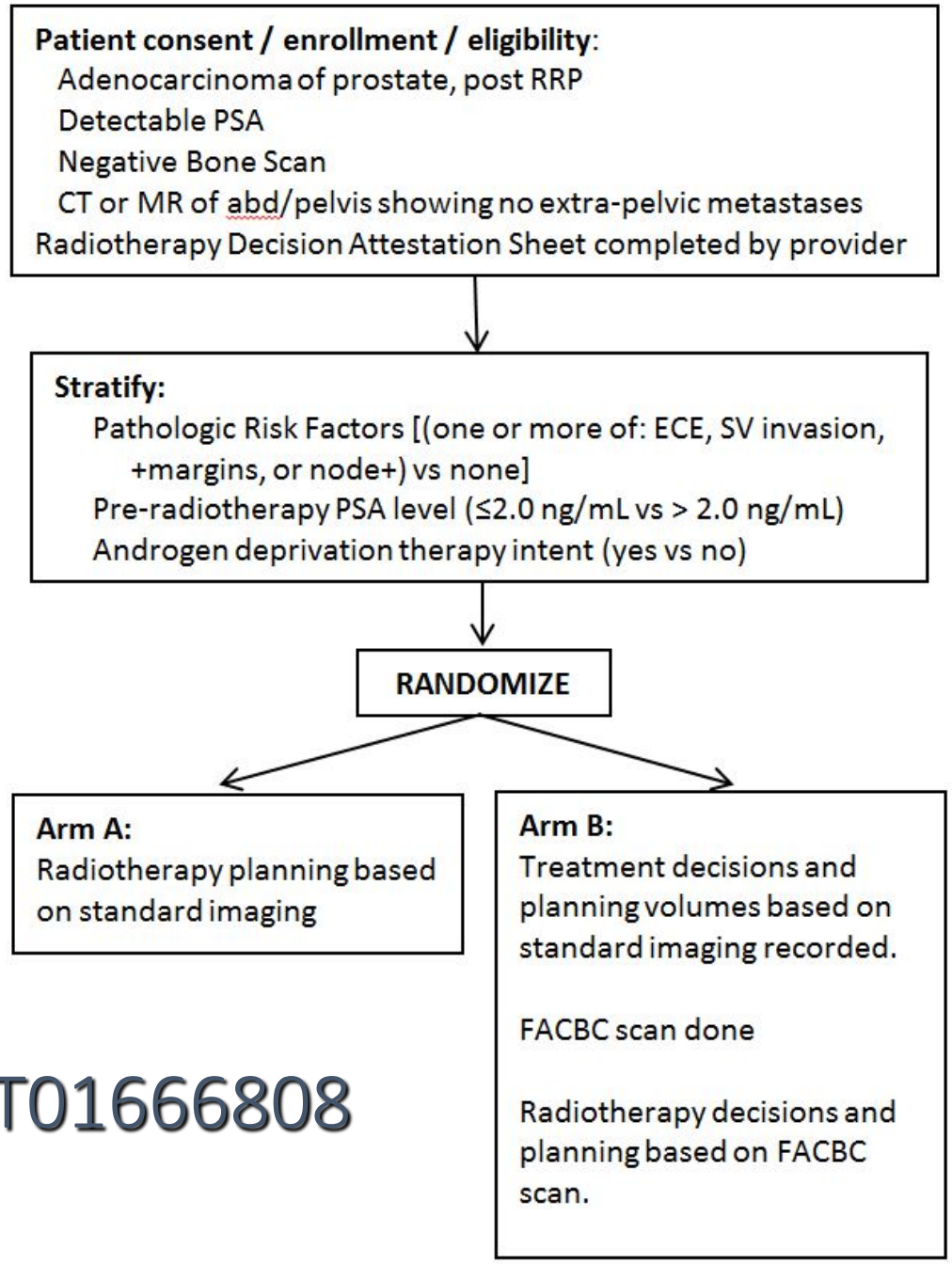
EMPIRE-1 Trial

Emory Molecular Prostate Imaging for Radiotherapy Enhancement



NIH RO1 CA169188

Jani & Schuster

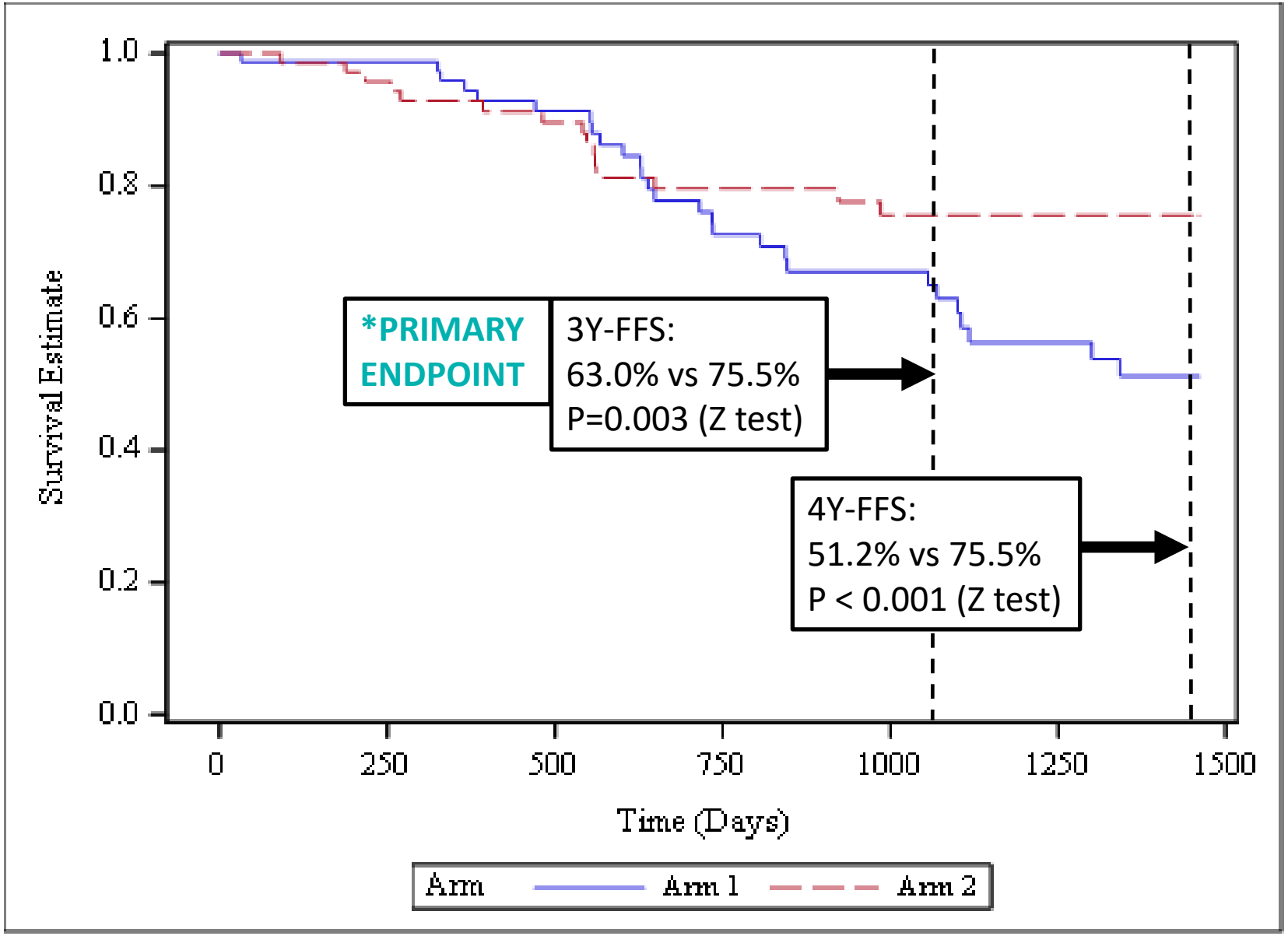
ClinicalTrials.gov: NCT01666808

Fluciclovine (^{18}F) Findings/ Treatment decision:

1. Extra-pelvic uptake:
   - Abort XRT
2. Pelvic nodal uptake:
   - Prostate bed (64.8-70.2/1.8Gy)
   - \+
   - Pelvis (40.5-50.4/1.8Gy)
3. Prostate-bed only uptake:
   - Prostate bed (64.8-70.2/1.8Gy)
4. No uptake:
   - Prostate bed (64.8-70.2/1.8Gy)

Failure-Free Survival

- Three years after treatment, failure-free survival rates were higher in the PET arm
- FFS benefit remained four years after treatment
- Median follow-up
  - Overall: 2.48 Y
  - Failure-free pts: 3.06 Y



Provider-Reported Toxicity
(CTCAE v.5.0)

No significant differences in maximum:

- Acute GU
- Acute GI
- Late GU
- Late GI

Suggests treatment to PET-directed volumes was tolerable.

Patient-reported toxicity (AUA & EPIC-CP) analysis pending

Acute GU (max)	Grade 0	Grade 1	Grade 2	Grade 3	P-value
Arm A/1 (no PET)	7 (8.64%)	53 (65.43%)	18 (22.22%)	3 (3.70%)	0.255
Arm B/2 (PET)	3 (3.95%)	55 (72.37%)	18 (23.68%)	0 (0.00%)	

Acute GI (max)	Grade 0	Grade 1	Grade 2	Grade 3	P-value
Arm A/1 (no PET)	23 (28.40%)	47 (58.02%)	11 (13.58%)	0 (0.00%)	0.436
Arm B/2 (PET)	18 (23.68%)	42 (55.26%)	16 (21.05%)	0 (0.00%)	

Late GU (max)	Grade 0	Grade 1	Grade 2	Grade 3	P-value
Arm A/1 (no PET)	6 (7.50%)	32 (40.00%)	37 (46.25%)	5 (6.25%)	0.678
Arm B/2 (PET)	10 (13.33%)	29 (38.67%)	31 (41.33%)	5 (6.67%)	

Late GI (max)	Grade 0	Grade 1	Grade 2	Grade 3	P-value
Arm A/1 (no PET)	47 (58.75%)	23 (28.75%)	10 (12.50%)	0 (0.00%)	0.580
Arm B/2 (PET)	49 (65.33%)	20 (26.67%)	6 (8.00%)	0 (0.00%)	

Conclusions/Summary

- Randomized trial of imaging tests with primary cancer control endpoint are important but uncommon
- First trial of PET over conventional imaging alone for post-prostatectomy radiation therapy (Note: single institution study where radiotracer was invented)
- **Inclusion of fluciclovine (^{18}F) resulted in significant improvement in failure rate at 3Y**

- Integration of novel PET radiotracers into XRT decisions and planning warrant further study

EMORY WINSHIP CANCER INSTITUTE

EMORY UNIVERSITY

EMPIRE-2 Trial

Emory Molecular Prostate Imaging for Radiotherapy Enhancement

NIH RO1 CA226992

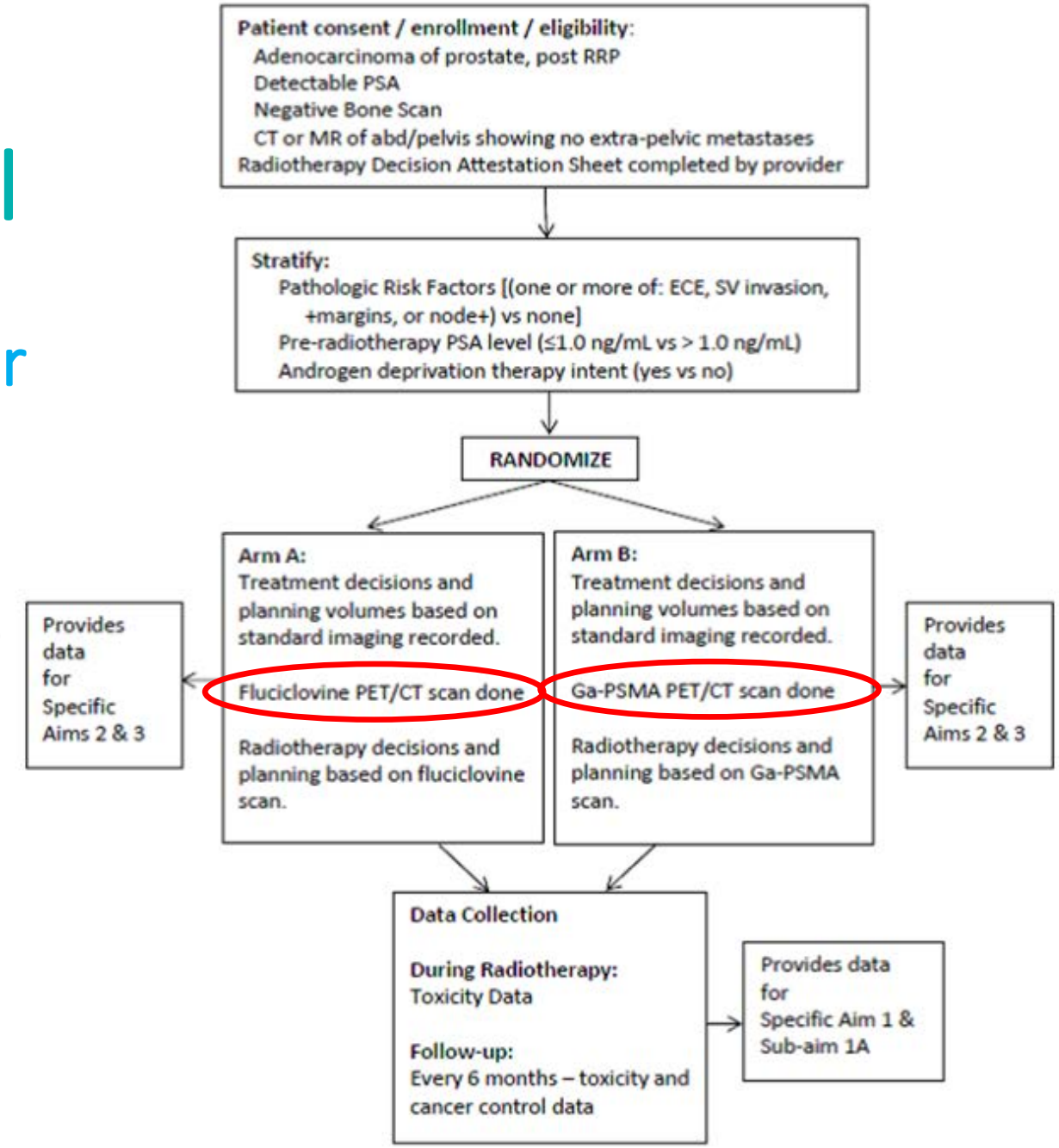
Jani & Schuster

ClinicalTrials.gov:

NCT03762759

2019-2024

n=140 (enrolled ~50)



PET Findings / Treatment decision:

1.
Extra-pelvic uptake:
Abort XRT

2.
Pelvic nodal uptake:
Prostate bed + Pelvis XRT
(Boost sites of uptake)

3.
Prostate-bed only uptake:
Prostate bed XRT
(Boost sites of uptake)

4.
No uptake:
Prostate bed XRT (no boost)

Boost:
Pelvic nodes: 54-56 Gy
Prostate bed: 70-76 Gy