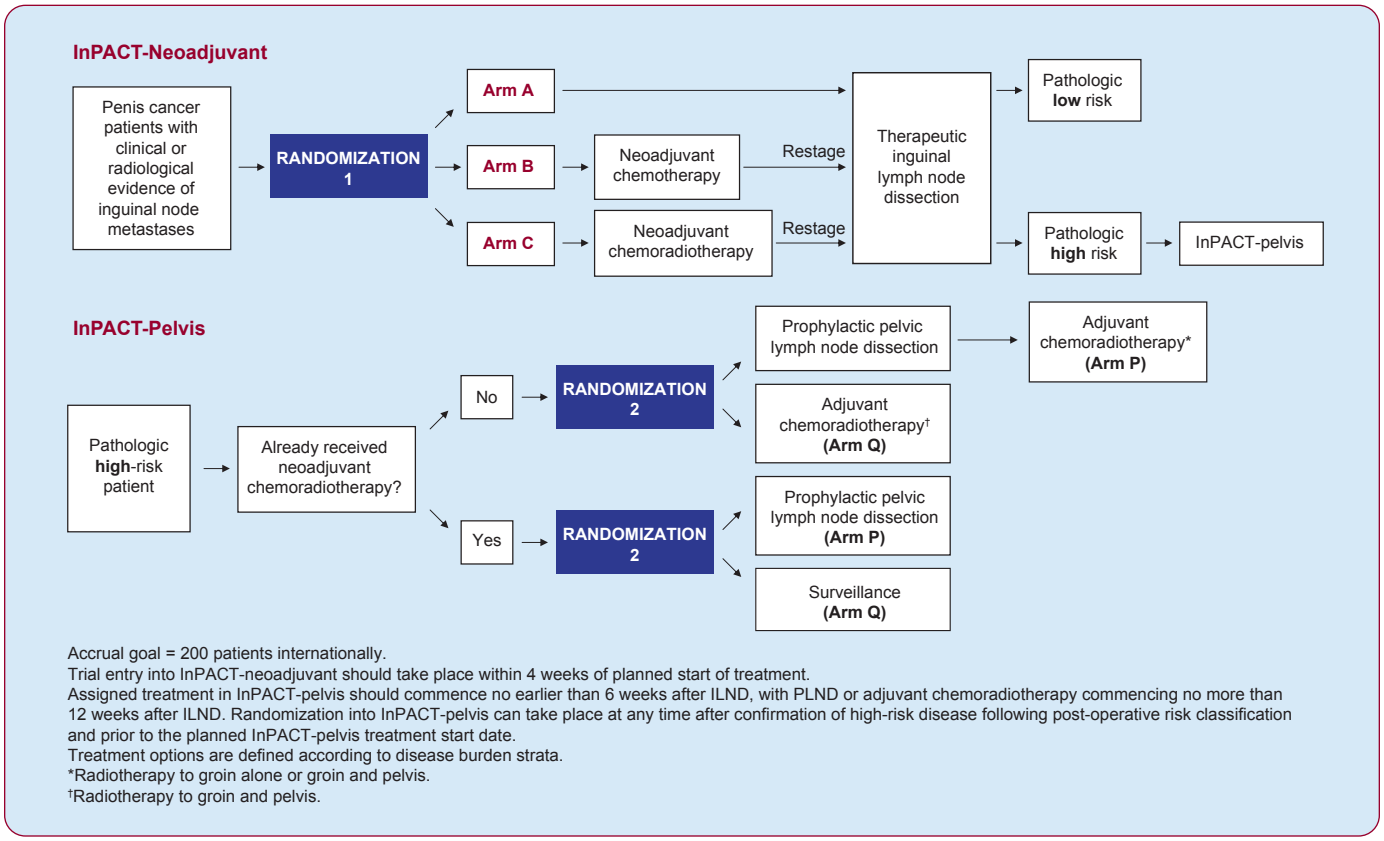
InPACT/EA8134

International Penile Advanced Cancer Trial (International Rare Cancers Initiative Study)

Overall Study Goal

To determine the optimal sequence of surgery, chemotherapy, and chemoradiotherapy in the routine clinical management of men with locally advanced squamous carcinoma of the penis (however, all patients with clinically positive nodes may be eligible)

Study Schema



Accrual goal = 200 patients internationally.
Trial entry into InPACT-neoadjuvant should take place within 4 weeks of planned start of treatment.
Assigned treatment in InPACT-pelvis should commence no earlier than 6 weeks after ILND, with PLND or adjuvant chemoradiotherapy commencing no more than 12 weeks after ILND. Randomization into InPACT-pelvis can take place at any time after confirmation of high-risk disease following post-operative risk classification and prior to the planned InPACT-pelvis treatment start date.
Treatment options are defined according to disease burden strata.
*Radiotherapy to groin alone or groin and pelvis.
†Radiotherapy to groin and pelvis.

How Your Site Can Participate

- **Before recruitment,** investigators must be registered members of a participating NCTN
- Investigators must have an active CTEP registration with credentials necessary to access secure NCI Clinical Oncology Research Enterprise (CORE) systems (this includes completing an annual registration via the Registration and Credential Repository [RCR] per US Appendix Section 1)
  - The site investigator must also be rostered at the site on the IRB approval, and as of 03/01/19, rostered on the NCI CIRB roster under a CIRB Signatory Institution(s) record (applicable to US-based sites)
  - For additional information, visit https://ctep.cancer.gov/investigatorResources/default.htm
  - For questions, contact RCRHelpDesk@nih.gov

InPACT/EA8134

- **Requirements for EA8134 site registration** (download the site registration forms from the EA8134 page located on the CTSU website):
  - IRB Approval:
    - Study Specific Worksheet approval for sites relying on the NCI CIRB
      - Sites participating with the NCI CIRB need not submit separate IRB approval documentation to CTSU for initial, continuing, or amendment review. For these sites, IRB data automatically load to RSS. Other site registration requirements (eg, lab or protocol-specific training certifications, modality credentialing) must be submitted to the CTSU Regulatory Office, or compliance communicated per protocol instructions
    - IRB Approval Letter or CTSU IRB Certification Form or HHS OMB No. 0990-0263 (replaced Form 310) for sites relying on their local IRB as the IRB of record

    Note: Submission includes all sites approved for the protocol under an assurance number; OHRP registration number of reviewing IRB; full protocol title and number; version date; type of review (full board vs expedited); date of review; signature of IRB official
  - Sites must be linked to at least one Imaging and Radiation Oncology Core (IROC) provider. To manage provider associations or to add/remove providers, access the Provider Association page on the CTSU member's website: https://www.ctsu.org/RSS/ RTFProviderAssociation
- **Submit all required regulatory documents to the CTSU Regulatory Office via the Regulatory Submission Portal on the CTSU website:**
  - Sites with patients waiting that are unable to use the Regulatory Submission Portal should contact the CTSU Regulatory Office at (866) 651-2878 or CTSURegHelp@coccg.org
- Check registration status at https://www.ctsu.org (Regulatory tab, Site Registration, Enter your 5-character CTEP site code)
- **Once documentation has been submitted and approved:**
  - Patient enrollment is via OPEN (https://open.ctsu.org), and data collection is via Medidata Rave; address questions to the CTSU Help Desk at 1-888-823-5923, Option 1 or ctsucontact@westat.com
  - TRIAD will be used for digital RT data submission; address questions to TRIAD-Support@acr.org
  - Patients must not start protocol treatment before randomization. Start radiotherapy as follows:
    - Neoadjuvant trial arm: 4 weeks after randomization
    - Postoperative trial arm: 8 weeks after randomization
- **Additional requirements before patient enrollment:**
  - Surgeon credentialing per US Appendix Section 4
  - Radiation therapy credentialing requirements per US Appendix Section 6
  - Pathology credentialing requirements per US Appendix Section 8
    - Training url: https://coccg813.learn.trakstar.com/PublicCoursePage.aspx?c=12858059528
    - For questions, contact EAClinEd@ecog-acrin.org
  - Radiology credentialing requirements per US Appendix Section 10; address questions to inpact@acr.org
- Enter and track all tumor tissue specimens using the ECOG-ACRIN Sample Tracking System (see US Appendix Section 14.3); address questions to ea.tst@ecog-acrin.org

Contact Information

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For Further Study Information

- For more information about the EA8134 study, please visit the following:
  - Clinicaltrials.gov; search NCT02305654
- For more information about ECOG-ACRIN, visit ecog-acrin.org

NCI National Clinical Trials Network

ECOG-ACRIN cancer research group