ClinicalTrials.gov Resources

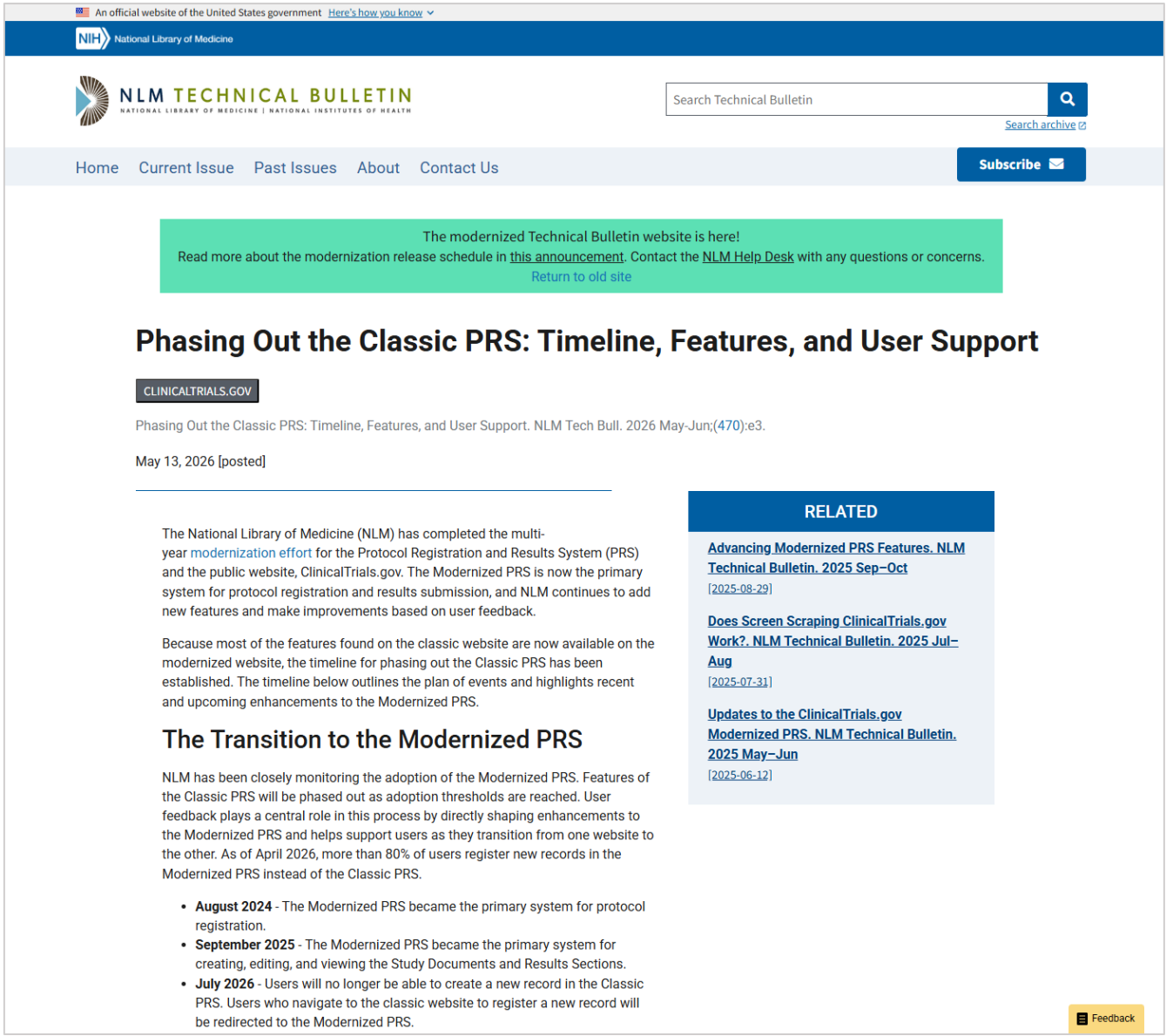
July 14, 22, 30, 2026

NIH National Library of Medicine

PRS Protocol Registration & Results System
ClinicalTrials.gov

NLM Technical Bulletin

nlm.nih.gov/pubs/techbull/mj26/mj26_ctg_prs.html



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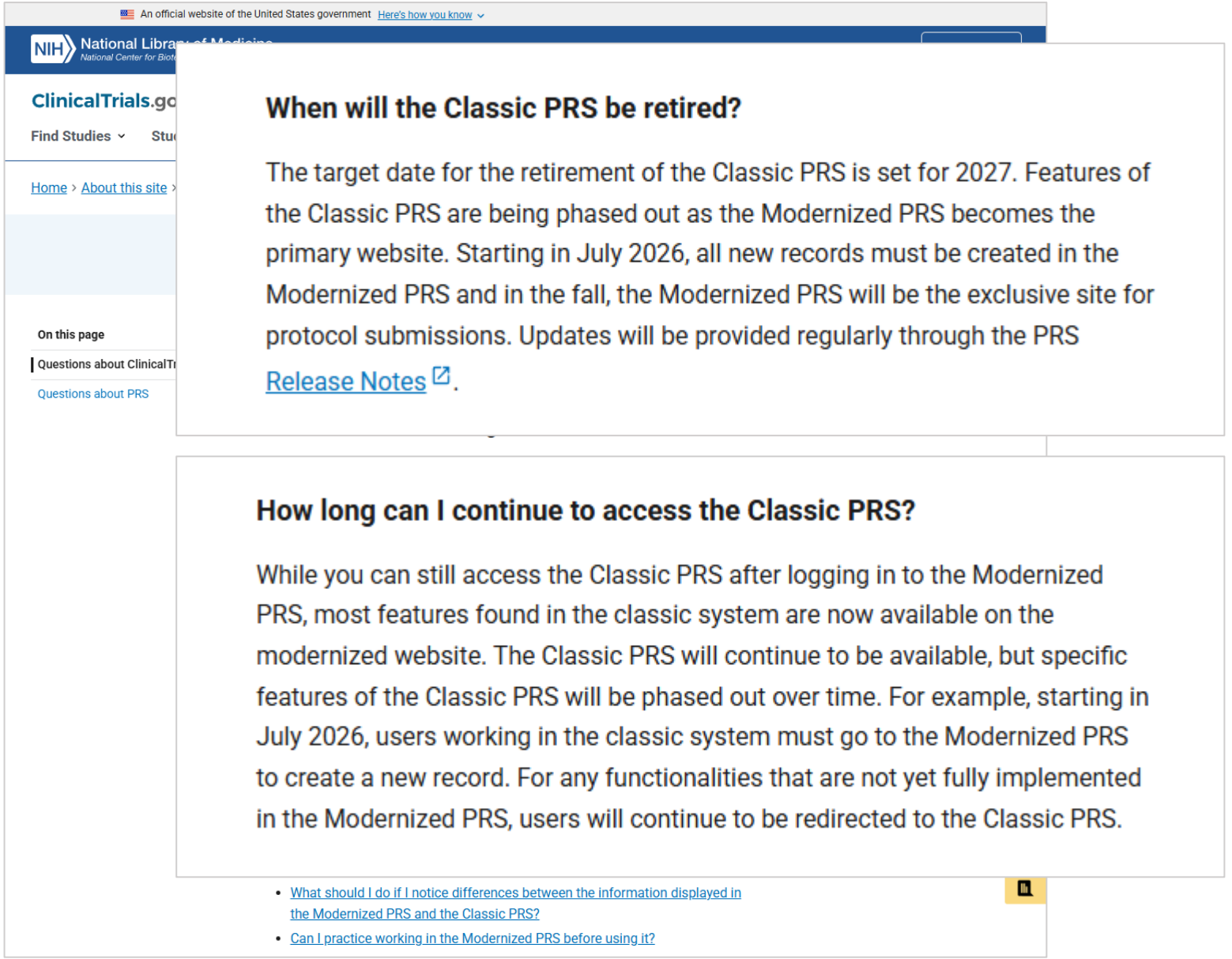
Transition to the Modernized PRS

Timeline for Phasing Out the Classic PRS

- *August 2024* - The Modernized PRS became the primary system for protocol registration.
- *September 2025* - The Modernized PRS became the primary system for creating, editing, and viewing the Study Documents and Results Sections.
- **July 2026** - **Users will no longer be able to create a new record in the Classic PRS.** Users who navigate to the classic website to create a new record will be redirected to the Modernized PRS.
- **Fall 2026** - All protocol submissions must be completed in the Modernized PRS.
- **2027 (target)** - The Classic PRS Results Section modules and XML upload feature will be phased out as adoption thresholds are met. NLM will continue to provide updates on the timeline to the full retirement of the Classic PRS.

Modernization Transition Top Questions

clinicaltrials.gov/about-site/modernization-top-questions



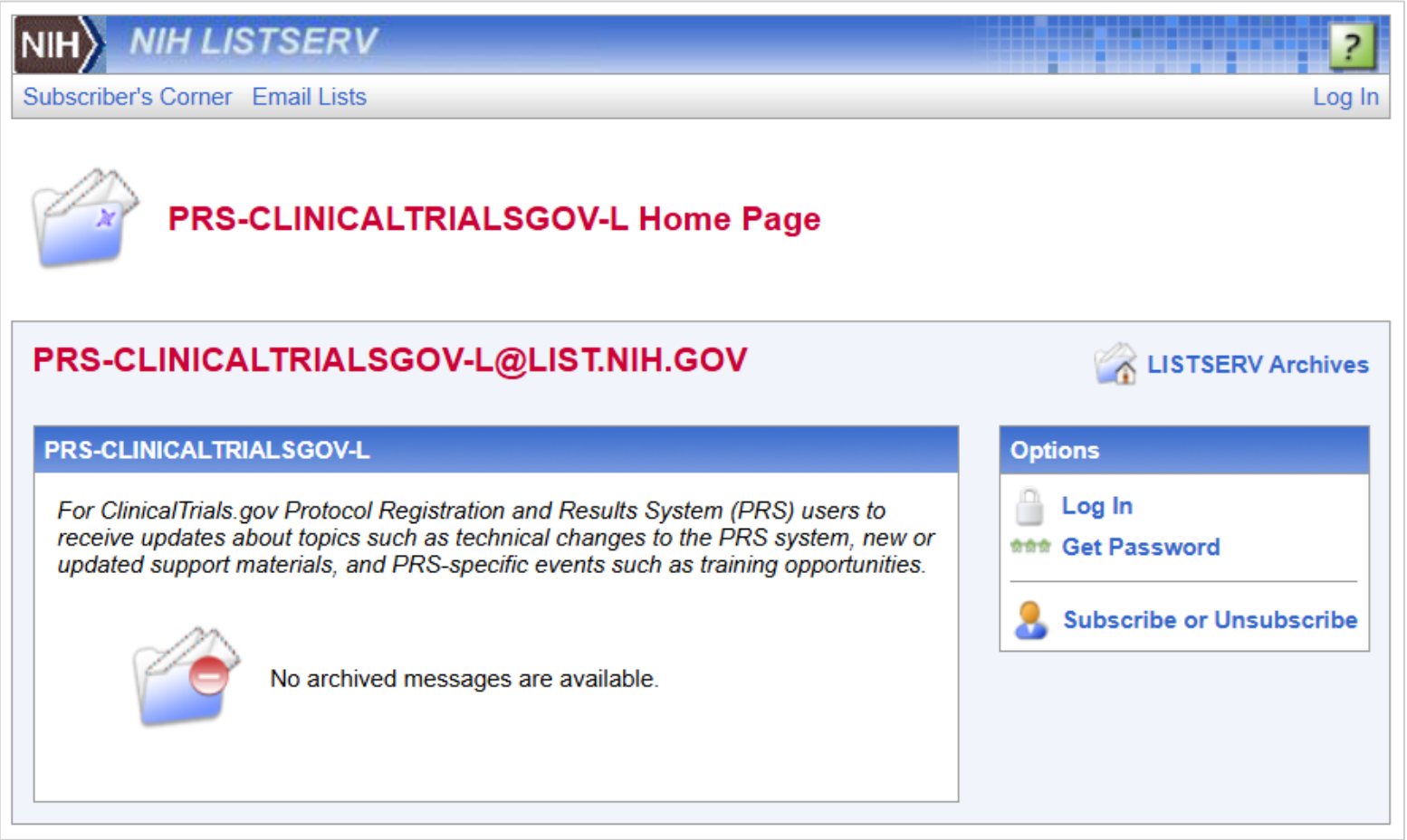
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PRS Protocol Registration & Results System
ClinicalTrials.gov

ClinicalTrials.gov PRS E-bulletin

ClinicalTrials.gov
PRS News and Updates

bit.ly/4vB1sLS



Helpful Resources

Contact
register@clinicaltrials.gov

FAQ: “Which trials must be registered on ClinicalTrials.gov?”
https://clinicaltrials.gov/policy/fdaaa-801-final-rule#WhichTrialsMustBeRegistered

Checklist and Elaboration for Evaluating Whether a Clinical Trial or Study is an Applicable Clinical
https://cdn.clinicaltrials.gov/documents/ACT_Checklist.pdf

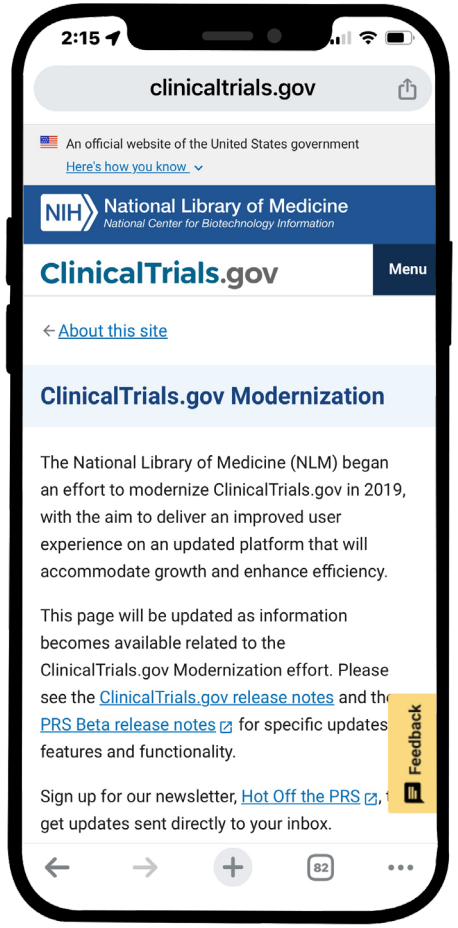
Support and Training Materials Page
https://clinicaltrials.gov/submit-studies/prs-help/support-training-materials

PRS Users Guide
https://clinicaltrials.gov/submit-studies/prs-help/user-guide

PRS Guided Tutorials
https://clinicaltrials.gov/submit-studies/prs-help/prs-guided-tutorials

Modernized PRS Guided Tutorials
https://clinicaltrials.gov/submit-studies/prs-help/modernized-prs-guided-tutorials

Other Ways to Learn More



ClinicalTrials.gov News and Updates
clinicaltrials.gov/about-site/news-and-updates

ClinicalTrials.gov Release Notes
clinicaltrials.gov/about-site/release-notes

PRS What's New
register.clinicaltrials.gov/prs/html/whats-new.html

PRS Release Notes
register.clinicaltrials.gov/prs/beta/public/release-notes-prod

Contact us
register@clinicaltrials.gov

Key Takeaways: ACT Determination for Device Trials

- **Consider whether the product is an FDA-regulated device**
  - CDRH mailboxes: DeviceDetermination@fda.hhs.gov, DigitalHealth@fda.hhs.gov
- **A device study can be an ACT whether or not an IDE submission is required.**
  - Nonsignificant risk and exempt device studies can be ACTs.
- **Studies involving diagnostic devices can be ACTs.**
  - ACTs are not limited to studies involving therapeutic interventions.
- **Certain feasibility studies are excluded as ACTs.**
  - Traditional feasibility studies can be ACTs.

Key Takeaways: Compliance and Reporting

- **The ‘Responsible Party’**
  - If ACT is under an IND, the IND holder is the Responsible Party
- **The 21-Day Registration Clock**
  - Register ACTs within 21 days of first enrollment
- **Results Reporting Deadlines**
  - Submit results within 1 year of the Primary Completion Date
- **Terminated Trials Still Require Results**
  - Early termination does not erase reporting requirements

Key Takeaways: FDA Office of Compliance

- Compliance is a regulatory obligation, not a best practice.
- Know the requirements, including reporting deadlines.
- Build system, not reminders.
- FDA is here to help, and to enforce.

Compliance is not optional, but it is achievable

Key Takeaways: FDA Office of Clinical Policy

- Other ClinicalTrials.gov Requirements
  - Informed Consent
  - Certification of Compliance (Form FDA 3674)

- Importance of Transparency

Questions?

gcpquestions@fda.hhs.gov

Key Takeaways:
FDA Center for Biologics Evaluation and Research

- ClinicalTrials.gov oversight activities are handled uniformly across FDA.
- Each ACT must have 1 Responsible Party who is the sponsor of the trial or an individual delegated to assume the duties.
- Rapid and unexpected personnel changes happen – update ClinicalTrials.gov with changes to the RP and contact information!
- Our focus is to educate and support – reach out when there are questions and uncertainties.

Key Takeaways:
FDA Center for Drug Evaluation and Research

- Compliance is a continuous responsibility
- Know who is responsible — and make sure they know it too
- Build institutional systems that outlast any one person
- FDA strives to promote voluntary compliance

Additional Helpful Resources

Frequently Asked Questions

- https://clinicaltrials.gov/policy/faq

Applicable Clinical Trials

- FDA's Role: https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/fdas-role-clinicaltrialsgov-information
- 42 CFR Part 11: https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-11
- ACT Checklist: https://cdn.clinicaltrials.gov/documents/ACT_Checklist.pdf

Protocol Registration and Results System

- User's Guide: https://clinicaltrials.gov/submit-studies/prs-help/user-guide
- Guided Tutorials
  - https://clinicaltrials.gov/submit-studies/prs-help/prs-guided-tutorials
  - https://clinicaltrials.gov/submit-studies/prs-help/modernized-prs-guided-tutorials