DirectTrust Health App and Digital Therapeutics accreditation consulting

Last reviewed October 2026 · https://www.integralhs.com/health-app-digital-therapeutics-accreditation

What to have ready

Each item below ties to DirectTrust's published program and process pages for the 2026 criteria versions (Health App v2.1, Digital Therapeutics v1.1, CARIN Code of Conduct v1.1). The criteria text itself comes from DirectTrust on request.

- The criteria document for your track, requested from DirectTrust through its Programs page (DirectTrust, Programs, opened October 3, 2026, accreditation.directtrust.org/programs/programs-overview).
- A decision on scope: Health App alone, Health App with the Digital Therapeutics add-on, or the CARIN program (DirectTrust, Programs, opened October 3, 2026, accreditation.directtrust.org/programs/programs-overview).
- Someone with authority to sign the Accreditation Program Agreement (DirectTrust, The Accreditation Process, opened October 3, 2026, accreditation.directtrust.org/about/accreditation-process).
- Revenue figures for the Financial Attestation (DirectTrust, The Accreditation Process, opened October 3, 2026, accreditation.directtrust.org/about/accreditation-process). DirectTrust sets fees by program, location and revenue level (DirectTrust, Apply, opened October 3, 2026, accreditation.directtrust.org/apply).
- A list of your locations. Fees vary with the number of locations (DirectTrust, Apply, opened October 3, 2026, accreditation.directtrust.org/apply), and a Location Review checks practice at the locations in scope (DirectTrust, The Accreditation Process, opened October 3, 2026, accreditation.directtrust.org/about/accreditation-process).
- Privacy and security records for health and wellness data held outside HIPAA, including how you handle the FTC Health Breach Notification Rule (DirectTrust, Health App, opened October 3, 2026, accreditation.directtrust.org/programs/health-app).
- For the CARIN option, consent records and data-sharing flows showing that data leaves the app only with the end user's knowledge and consent (DirectTrust, Health App, opened October 3, 2026, accreditation.directtrust.org/programs/health-app).
- For a digital therapeutic, the evidence your clinical leads hold on efficacy, data privacy and security (DirectTrust, Digital Therapeutics, opened October 3, 2026, accreditation.directtrust.org/programs/digital-therapeutics).
- Written procedures that match how the team works, because a Location Review compares the documented practices with what happens in daily operations (DirectTrust, The Accreditation Process, opened October 3, 2026, accreditation.directtrust.org/about/accreditation-process).