# Ensuring the usability of health IT products

**Helping our clients ensure the usability, safety, and effectiveness of HIT products**

Electronic health records products are an essential piece of the healthcare solution. However, it is important to take steps to protect patient data. The Office of the National Coordination (ONC) for Health Information Technology (HIT) Health IT Certification Program supports programs for users of electronic health records software programs and other health IT products. It is a voluntary conformity assessment program that demonstrates your commitment to patient privacy and information security. UL can guide you through the complete process, from understanding the requirements to testing and certification.

## How can UL help you?

**Software Testing & Certification**

- Pre-testing compliance guidance
- ONC testing
- ONC certification listing
- Electronic Prescribing for Control Substance (EPCS) testing and certification

**User Experience Research & Design**

- UI design support
- Usability testing (formative, summative, benchmarking)
- User-centered design / UX strategy planning

## UL is an accredited ONC HIT testing lab and certification body

- UL is authorized by the U.S. Department of Health and Human Services (HHS) ONC to test and certify EHR products as an accredited testing laboratory and ONC-authorized Certification Body.
- Testing for your product can be performed at your facility, on-site at the UL lab in California, or remotely. The optimal testing process and procedures are determined with your input.
- To minimize test time and ensure your product is ready for testing, UL offers regulatory training to help your developers understand the ONC HIT program requirements.

## EMPOWERING TRUST™ through our Experts

- UL is staffed with PHD's, MS's and MD's in Human Factors Engineering (HFE), industrial design, graphic/visual design, and mechanical engineering
- 2 Professors that teach human factors and design at local universities
- HFE experts that have authored multiple books and standards for the industry
- Our team holds degrees in technical fields, Computer Science, Information Systems and Engineering

# UL Process

1. Define a vision of the user experience
2. Identify specific user needs and preferences
3. Provide user interface design support
4. Conduct early-stage user experience research
5. Conduct summative usability tests
6. Conduct design critiques
7. Conduct user research strategy plan
8. Assess and mitigate use-related risk
9. Provide usability guidance during implementation
10. Prepare documentation
11. Deliver workshops and seminars

# ONC HIT Certification Process

1. The UL Certification Body performs a review of the Health IT Module Test Report received from an NVLAP accredited testing laboratory to determine if the product qualifies for certification.
2. If additional testing is required, the Certification Body works with the testing laboratory to address issues that require further clarification.
3. Once all testing has been successfully completed, the Certification Body certifies the Health IT Module and submits the product information to ONC for posting on the CHPL website.
4. The application developer will be provided with the ONC Certified HIT Mark indicating that the product is certified under the ONC Health IT Program.

**Other Resources:**

https://industries.ul.com/healthcare/engineering-disciplines/digital-health/onc-health-it-testing-and-certification
https://www.gpo.gov/fdsys/pkg/FR-2012-03-07/pdf/2012-4430.pdf

# Standards

- Technical leadership in HIT usability

- Guidance documents

UL's user experience and human factors team is currently leading the development of two AAMI guidance documents related to health IT usability, including a user-centered design process guide and set of UI design guidelines.

Both guidance documents are based on a multi-year project UL completed for the National Institutes for Standards and Technology (NIST) regarding EHR usability. The project resulted in the following technical report: NIST GCR 15-996, Technical Basis for User Interface Design of Health IT.

The report outlines a development process that includes the user interface development stages described above. Furthermore, the report contains over 300 practical guidelines on EHR user interface design.

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# Empowering Trust™