



Digital Health & Software: evidence guidance

Version 1.0 | 13 October 2026

Prepare the evidence for a digital health & software entry. This guide covers the product details, reports and use information reviewers need.

Explain the task and output

Describe users, inputs, outputs and the action supported. Distinguish information, monitoring and decision-support functions. State limits, including when an output should not be relied on.

Provide versioned validation

Map evidence to the release, algorithm and data configuration. Explain evaluation methods, sources, exclusions and limitations. For adaptive or frequently updated systems, describe change control and the relation between the evaluated and deployed versions.

Show the workflow and support arrangements

Provide a recording or restricted demonstration using simulated or appropriately de-identified data, with a short route through important tasks. Do not provide patient accounts or production administrator credentials. Explain relevant permissions, security, accessibility, incident handling and update support. Marketing websites and general health articles alone are outside this category.

Evidence checklist

Area	Required material	Check before submitting
Definition	Function, users, workflow, release and dependencies	User and professional responsibilities are clear.
Validation	Evaluation methods, data, findings and version mapping	Material gaps between evaluation and deployment are explained.
Demonstration	Stable link, limited access and English task instructions	Tasks are reviewable without exposing personal data.
Data and security	Relevant flows, permissions, evaluation and incident arrangements	Materials concern the actual product and its risks.
Updates	Change control, revalidation and support	Changes affecting evidence or scope can be identified.

Preparing review access

Limit the demonstration account to required functions, use simulated data and explain intentional differences from the supplied product. Keep access available during review. Provide a recording where interactive access is impractical. Never grant access to live clinical or production systems.



A report for release 2.1 does not automatically support release 3.0. Identify changed functions, explain evidence that remains applicable and provide relevant new validation.

Map claims to sources

For each principal claim, record its exact wording, report or study, file and page, assessed version, method or population, finding and limitation. Identify the author and relevant relationship with the applicant. Explain how evidence about a different formulation, component or version applies to your product.

Prepare readable files

Supply readable reports, with the original and relevant English passages where needed. Keep private reports separate from proposed public information. Remove personal information not needed for review.

The entry permits up to 20 attachments and 250 MB in total: 25 MB per PDF and 10 MB per image. Video is supplied by link. Contact the awards team if an essential report exceeds these limits.

[Return to the category](#) · [Use the evidence worksheet](#) · [Read the rubric](#)