

# Text on cMHAFF in CEN/ISO HaWA

In the HaWa specs "de-verbosing" is the current topic. In that respect it has been suggested to minimize the reference to cMHAFF according to the following action:

- 20200622\_actions: Frank to draft suggested text for HL7 cMHAFF (maybe in Annex A - *(Informative) Rationale for scope* - rather than as the whole annex)
- As of now, cMHAFF is described in Annex E (informative): *Relationship to HL7 Consumer Mobile Health Application Functional Framework*

Suggested rewrite:

// start text

The HL7 consumer Mobile Health Application Functional Framework (cMHAFF) is an HL7 Standard for Trial Use (STU). The primary goals of HL7 cMHAFF are to provide a standard against which a mobile app's foundational characteristics -- including but not limited to security, privacy, data access, data export, and transparency/disclosure of conditions -- can be assessed.

The framework is based on the lifecycle of an app (<https://cmhaff.healthservice.com/Standard/Overview/TabId/1034/ArtMID/3808/ArticleID/21202/2-Overview.aspx>), as experienced by an individual consumer, from first deciding to download an app, to determining what happens with consumer data after the app has been deleted from a smartphone. It is important to note that the Framework does *not* speak directly to the specific health or clinical functionality of an app but can be extended to do so through the use of profiles (with constraints and/or extensions) developed on top of HL7 cMHAFF.

The site <https://cmhaff.healthservice.com/> provides a visual overview of the HL7 CMHAFF STU and application for piloting cMHAFF use in testing and potential for certification of health apps.

## Relationship with EN-ISO/IEC DTS 82304-2

The HL7 cMHAFF standard has a *standard trial use* (STU) status and is due to become a formal standard in 2021 (ANSI approval). Balloting for normative standard is targeted for May 2021.

During this same period the EN-ISO/IEC TS 82304-2 will run its course.

## Alignment of cMHAFF to EN-ISO/IEC DTS 82304-2

During the development cycle of the CEN/ISO specification, HL7 cMHAFF will work to harmonize efforts to better align with:

- definitions: preferably taken from the [Standards Knowledge Management Tool \(SKTM\) glossary](#);
- definitions: <https://www.iso.org/obp/ui>;
- **(CEN/ISO specifications related to the subject matter of cMHAFF and 82304-2)** conformance statement levels;

## The formal relationship between HL7 cMHAFF and the EN-ISO/IEC DTS 82304-2

HL7 is formally aligned with the EN-ISO/IEC DTS 82304-2 through the participation of an HL7 cMHAFF co-author in the CEN/ISO project. Extensive effort has been put into aligning the QRCA section of EN-ISO/IEC DTS 82304-2 with relevant parts of HL7 cMHAFF. **Where applicable it has so been noted in TS 82304-2.** The parts where both HL7 cMHAFF and a CEN/ISO standard would apply, the CEN/ISO reference was inserted. Vice-versa alignment will be undertaken on HL7 cMHAFF's part, after the technical specification (82304-2) is published by ISO TC215 (targeted for December 2020).

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Actions

- Seek approval by the CEN/ISO community;
- Seek approval by the HL7 community, a.k.a. HL7 HQ;
- execute alignment;
- setup plan for profiling.