

Attachment 1: ORCHA Baseline Review (OBR) Process

ORCHA's Baseline Review (OBR) Process is a process used to analyse and assess a Digital Health product or service to ensure that it meets all relevant regulatory standards and guidance. This process helps identify Digital Health Solutions that have the potential to support specific service aspects, clinical outcomes, strategic aims or particular cohorts of the population.

The OBR involves a detailed desktop analysis, looking across all of the key areas of regulation and compliance. The OBR is primarily an assessment of an App's compliance with all current standards, regulation and good practice, including those of NHSD/NHSX: <https://digital.nhs.uk/about-nhs-digital/our-work/nhs-digital-data-and-technology-standards/framework>.

The OBR evaluation process is bespoke to the nature of each individual App. This is because each App will be assigned a **Functional Level** and **Review Domain** which is dependent on the intended use of that particular App.

The OBR Functional Levels

In order to assess and score these Apps in a way that enables a fair comparison of like for like solutions, ORCHA devised a sequence of levels to attribute to an App. Levels 0-4 are indicative of the area of focus an App has (wellbeing, general health or specific conditions) and the level of functional complexity and associated risk. The levels are an important part of the ORCHA Baseline scoring system which adjusts between each level to reflect a shifting prioritisation based on measures of user experience of the data security and clinical assurance review domains.

Level 0 – Simple Wellbeing: Apps are designed to support general wellbeing, have limited feature sets and don't collect any data. Because they are not health focussed and do not collect data, compliance is only assessed in the User Experience domain.

Level 1 – Advanced Wellbeing: As above, but Apps can collect data and they are likely to have a number of more advanced features. Because they are not health focused their compliance is only assessed in the Data, Security and User Experience domains.

Level 2 – General Health: As above but where they collect data, data use policies and compliance with relevant standards are assessed. Because they are health focused Clinical Effectiveness compliance is also assessed as well as in the User Experience domains.

Level 3 – Condition Management: Apps can be focused on general health or support specific health conditions. They may collect data and they may have a number of more advanced features. Where they collect data, data use policies and compliance with relevant standards are assessed. Because they are health focused they also assess their compliance in the Clinical Effectiveness as well as in the User Experience domains.

Level 4 – Regulated: Apps can be focused on general health or specific conditions and contain advanced and complex features that are subject to formal regulation. Where they collect data, data use policies and compliance with relevant standards are assessed. Because they are health focused their compliance in the Clinical Effectiveness as well as in the User Experience domains is assessed.

The OBR Review Domains - Data Security; Clinical Assurance; and User Experience.

The review dynamically adjusts if the type or characteristics of an App evolves. This dynamic adjustment is a crucial part of the process, recognising that there are many different types of health Apps and that applying a blanket assessment model is highly inefficient and ineffective.

Domain 1 – Data Security: what information an App collects from users, what is done with that information and secure handling of the data.

Domain 2 – Clinical Assurance: what evidence there is of a suitably qualified professional or organisation being behind the development of the App or that it has been endorsed, accredited or underwritten by such an individual or organisation. This gives a sense of whether or not the App has appropriate professional input and guidance and aligns to one of the required standards of evidence for Lower Tier Apps under the recently published **Evidence Standards Framework for Digital Health Technologies by NICE.**

Domain 3 – User Experience: how an App has been designed to support overall user experience.

The OBR is constantly being iterated. The Review Development Team meet quarterly to review developments in the market, emerging regulations, standards and best practice and any other relevant inputs.

The ORCHA Score aims to deliver a meritocratic, fair and equal evaluation of Apps irrespective of their popularity or the financial position of their developer.

Any Application that scores over 65% against the Sub-Category/Condition specific review process is awarded a place on the DPS.

Medical Device Regulation (MDR)

A supplier must comply with the medical device regulations <https://www.gov.uk/guidance/medical-devices-eu-regulations-for-mdr-and-ivdr>.

ORCHA Recall Process – Yellow Card process

There are a number of questions within the Clinical Assurance Domain 2 which look at Medical Device Regulations to indicate whether the App is considered a Medical Device, in which case it must comply with the above regulations. There is leeway to allow the developer to maintain, amend or withdraw the functionality.

For more information around the Yellow Card Scheme see here <https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/>.