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G-Cloud 12 - Services Descriptions

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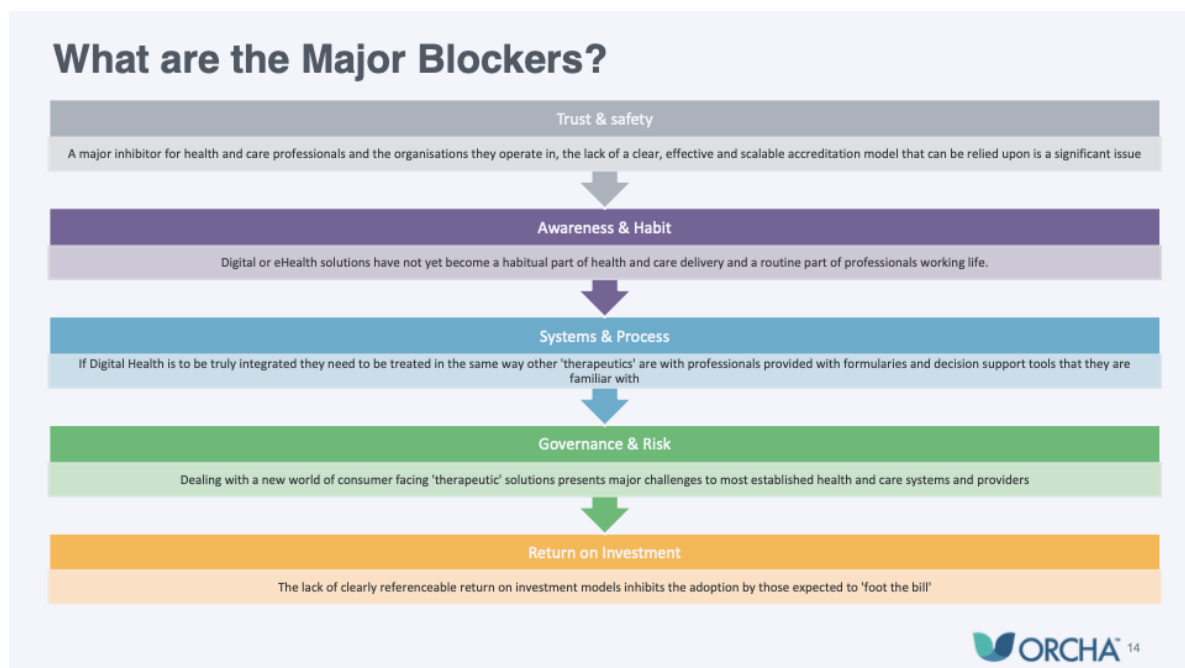
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1 Introduction/ Overview

ORCHA are the world's leading provider of Digital Health accreditation, dissemination, activation support and pathway integration services. Our mission is to get more people using great Digital Health solutions to improve their health and wellbeing and better manage conditions and illnesses.

Our vision is that within the next 5 years, Digital Health solutions will be an integral part of health and care delivery across all care settings and will be fully integrated with mainstream health and care services. We believe that this will be the catalyst for a revolution in the uptake in these solutions, sustaining and transforming beleaguered health and care systems whilst extending access to care for all, in a safe and affordable manner.

The ORCHA suite of products and services have been developed to help health and care organisations and systems to overcome the key barriers to widespread engagement, integration with and adoption of Digital Health solutions. These are summarised below:



Our solutions support health and care organisations and systems on their journey to true Digital Health integration. They provide incremental components that allow this journey to be taken at the pace most appropriate to the organisation and environment in question.

We have already supported over 70 health and care organisations, local and national, in all care settings on their Digital Health journeys. We have over 3,000 health and care professionals in the UK and internationally engaging with ORCHA as part of their drive to introduce Digital Health into their practices. Our solutions have evolved and developed in response to the insights and experience gained from these thousands of interactions and in response to the rapidly changing and evolving world of Digital Health itself.

ORCHA's unique suite of products and services provides a health and care system or individual organisation with a clear roadmap to fully embedding Digital Health solutions into their mainstream health and care services.

- Underpinning it is a foundation layer of robust and reliable Digital Health Assessment and Accreditation.
- Building on this is a clear approach to promote and disseminate the results of that assessment process to relevant target audiences via online 'libraries' catalogues and portals of Digital Health solutions.
- Super charging the dissemination and promotion of these solutions requires the leveraging of and active engagement by the health and care professionals that engage on a daily basis with core and often hard to reach members of the target community.
- Pulling all of this into a coordinated and well governed and managed approach within a relevant care setting requires organisations or systems to engage in Digital Care Pathway Integration processes which will ultimately provide the right vehicle for the commissioning of these solutions as integral parts of the overall delivery model.

2 Service Overview

	Review & Accreditation Services	Digital Health Portals	Pro-Solutions	Additional Services
Service Components	<ul style="list-style-type: none"> • Standalone Reviews 	<ul style="list-style-type: none"> • Content Curation 	<ul style="list-style-type: none"> • The ORCHA Transformation Model 	<ul style="list-style-type: none"> • Data Insights

	Review & Accreditation Services	Digital Health Portals	Pro-Solutions	Additional Services
	<ul style="list-style-type: none"> • Accreditation Design • Accreditation Build & Test • Accreditation Delivery • Performance Reporting 	<ul style="list-style-type: none"> • User Views and Controls • Digital Health Finder • Portal Configuration • My ORCHA • Portal Promotion • Performance Reporting 	<ul style="list-style-type: none"> • Digital Health Commissioning • Digital Health Data Integration Support • Digital Health Formularies • 'App' Prescribing • Digital Health Training • Micro-Accreditation & Peer Reviews • Data and Insights 	<ul style="list-style-type: none"> • User Focus Groups • Digital Attitude Surveys • Enhanced Programme Evaluation • Case Study Development

3 ORCHA Reviews and Accreditation Services

3.1 Background

Accreditation of Digital Health solutions is a fundamental foundation for their wider adoption and integration into health and care settings. It is clear that without a trusted accreditation approach, health and care organisations (and the professionals within them) simply can not develop the confidence needed to start to embed these novel products into their day to day practice and processes¹.

Digital Health Accreditation however poses major challenges to all health systems globally. Whilst most advanced jurisdictions recognise the advantages that Digital Health can offer, most (if not all) existing technology accreditation or evaluation models and approaches are

¹ <https://mhealth.jmir.org/2020/7/e17704/>

simply not up to the unique challenges that the world of mobile Apps and digital services present.

The key accreditation challenges are:

- Achieving sufficient assessment rigor in a cost effective and pragmatic manner
- Balancing the level of rigor with the need to maintain product and service owner (Developer) engagement
- Managing the rapid change cycle that most (good) digital health solutions adopt – and the associated re-assessment burden
- Managing the requirement to regularly update accreditation models as new regulations, guidance and technologies emerge – and the associated re-assessment burden
- Delivering sufficient volume of accredited solutions from a standing start to support local demand/opportunity in a cost effective manner
- Funding a new system of governance and accreditation and sharing these costs equitably across the system.
- The number of different solutions that are now available are in the hundreds of thousands and traditional models are not designed to cope with this volume of distinct products reliant as they almost universally are on an expert-based evaluation approach.

ORCHA provides a unique solution to all these challenges many of which are founded on the layering principle outlined below.

ORCHA Review Layers

All ORCHA Reviews are incremental and follow a layering principle. The foundation for all our Reviews is the ORCHA Baseline Review (“**OBR**”). The OBR is in its own right one of the most robust Digital Health assessments currently available and now forms the foundation for a growing number of national and regional accreditation models. More detail on the OBR can be found [here](#).

The second layer of ORCHA Reviews is the ORCHA Enhanced Review (“**OER**”). The OER is made up of a series of Enhanced Review Components (“**ERC’s**”). These are distinct assessment modules that build on the foundation of the OBR Review Domains, but look at the specific areas in much more detail. There are currently 7 ERC’s available (see table below) and new ERC’s are continuously being

developed as new assessment areas are developed and explored through our continuing research programmes and collaborations.

ERC	Review Domain
User/Patient Experience Analysis	Usability and Accessibility/ Professional/Clinical Assurance
Specialist Clinical Assessment	Professional/Clinical Assurance
Commercial & Financial Stability	Commercial
Enhanced Evidence Assessment	Professional/Clinical Assurance
Clinical Safety Analysis	Professional/Clinical Assurance
Enhanced Data Analysis	Data and Privacy
Security and Technical Stability Assessment	Security and Technical

The final layer of ORCHA Reviews are Client Specific Reviews (“**CSR’s**”). CSR’s are bespoke assessment elements that support a specific Client requirement. These can be specific to the underpinning use case of an accreditation model, or relate to specific requirements of the geography or jurisdiction that a Client is operating in.

The key advantage of the layered approach is that it allows for the sharing of the accreditation burden across multiple accrediting bodies by reducing assessment duplication and maximising the sharing of assessment data. This principle is also a key method of engaging the wider Digital Health market and the key Developer community as it reduces the accreditation burden on these organisation as more and more accrediting bodies adopt this common approach to building their specific accreditation models. This also helps ensure that the right balance can be maintained between the potentially conflicting goals of rigour and process attractiveness, ensuring as many great products and services are available in a given jurisdiction as possible.

The ability for accrediting bodies to join the ORCHA Accreditation Community and immediately share in the hundreds of accreditations across all the layers, that have already been undertaken, ensures that gaining credible volumes of approved solutions rapidly can be achieved cost effectively.

3.2 Standalone Reviews

All ORCHA Reviews can be purchased on a stand alone basis. The table below illustrates the types of reviews that ORCHA can deliver on a stand alone basis. The foundation assessment is the OBR and this includes a significant level of analysis of a products compliance with relevant regulations, standards and best practice.

The second layer of the assessment model adds the additional elements of assessment required for the emerging ISO 82304-2 standard.

The OER's are split into Bronze, Silver and Gold levels each adding more elements of ERC's.

The final option is to create a bespoke assessment built from the relevant ORCHA review components and with the ability to add in specific Client Review Components (CRC's) that are specific to a particular country or area of focus or client use case.

3.2.1 Standalone Review - Service Components

ORCHA Baseline Review (OBR)	OBR + ISO 82304-2	ORCHA Enhanced Review (Bronze)	ORCHA Enhanced Review (Silver)	ORCHA Enhanced Review (Gold)	Bespoke Assessment***
£499*	c£1,550	£1,100	£ 1,900	£2,750	£ TBD
	OBR +	OBR +	ORCHA Enhanced Review (Bronze) +	ORCHA Enhanced Review (Silver) +	Selection of:

ORCHA Baseline Review (OBR)	OBR + ISO 82304-2	ORCHA Enhanced Review (Bronze)	ORCHA Enhanced Review (Silver)	ORCHA Enhanced Review (Gold)	Bespoke Assessment***
Category/s	Additional ISO Components**	Specialist Clinical Assessment	Clinical Safety/Risk Analysis**	Enhanced Evidence Assessment	OBR - £499***
Features & Functions		User Experience Analysis	Enhanced Data Compliance**	Security & Technical Stability**	Specialist Clinical Assessment - £450
Target Audience			Commercial & Financial Analysis		Enhanced Data Compliance** - £250
Pricing/Commercial Model					User Experience Analysis - £250
Works With					Security & Technical Stability - from £700
Accreditations					Clinical Safety/Risk Analysis** - £250
Data Collection and Use					Enhanced Evidence Assessment - £400
Data Privacy/Protection Compliance					Commercial & Financial Analysis - £300

ORCHA Baseline Review (OBR)	OBR + ISO 82304-2	ORCHA Enhanced Review (Bronze)	ORCHA Enhanced Review (Silver)	ORCHA Enhanced Review (Gold)	Bespoke Assessment***
Professional Endorsements					Client Review Components - £TBD
Evidence of Efficacy					ISO Assessment Additions - £TBD**
Medical Device Compliance					
Usability and Accessibility					
Support Model					

*This is the cost for 1 review of a product on all platforms. If a product has more than 1 primary condition or sub-condition focussed module, each additional module costs £135. Discounts are available for the purchase of multiple reviews.

**Dependant upon engagement and cooperation of the relevant product owner/developer.

***Note: the ERC charges indicated here are for the Stand Alone - one off - Reviews. For Clients purchasing the Review and Accreditation Development and Delivery service these unit costs will be reduced by the scale of accreditations processed.

A stand alone Review can be undertaken on any Digital Health solution. In many cases, some or all elements of the Review will already exist within the ORCHA Database (especially the OBR). Where additional elements are required to be undertaken, these will (subject to their being no dependencies on the product owner/developer) be completed within 30 days of a purchase.

The Review output is an Assessment Report (available online through the My ORCHA Account and in a downloadable PDF format), that details all of the key findings from the relevant Review layers. In addition each Review includes a consultation session with the relevant ORCHA Reviewer to discuss the Review findings and deal with any queries arising from the Assessment Report.

Clients can also include and option for ongoing product monitoring, re-reviews and alerts as part of their stand alone review. This will ensure that they are alerted to any changes in a relevant product and the product is re-assessed to ascertain if there have been any material changes to its assessment status. This is all delivered via the My ORCHA Account and related alert channels (email/sms).

It should be noted that all OBR Data (and Reviews) is included with a purchase of an ORCHA Digital Health Hub (see below) or for a Client purchasing the ORCHA Review and Accreditation service (see below) and so any client looking at purchasing multiple Reviews on a regular basis should look at these as potential alternative options.

3.3 Digital Health Accreditation Development and Delivery

For organisations that are looking to develop a Digital Health accreditation process - typically national or regional bodies looking to establish a relevant 'geographical' accreditation regime - it is crucial that they have the ability to tailor the relevant review components and the relevant 'scoring' principles and thresholds, to their specific use cases and jurisdictions/geographies. In addition, they will want to be able to undertake or oversee, multiple accreditations using this model. The Stand Alone Reviews will therefore, generally, not meet these needs

The ORCHA Review and Accreditation service, has been developed to meet the specific needs of these bodies and to allow for the creation of bespoke Review models, whilst retaining as far as possible the benefits of shared assessment data and the underpinning foundations of the OBR. The build, test and delivery elements of this process are all delivered by the ORCHA Review Engine described below. Wrapping around this is a full range of consultative services we can offer to aid with the design of the assessment itself.

It should be noted that all Client Accreditations automatically include a tailored instance of the ORCHA Digital Health Portal (see below) where the results of that Client Accreditation process are displayed. The Portal can be configured in multiple ways and can be 'public facing' or restricted access. Client Accreditation data can also be provided through an API to an alternative 'front end' solution. The various pricing implications of each of these options is dealt with in the pricing summary.

The ORCHA Review and Accreditation Service includes the following elements:

Review & Accreditation Service					
Accreditation Design <ul style="list-style-type: none"> • Content Design (Optional) • Scoring Design (Optional) • Process Design (Optional) • Portal Design (Core) 	Accreditation Build & Test (Core) <ul style="list-style-type: none"> • Content Build • Scoring Build • Workflow Development • Portal Build 	Accreditation Delivery <ul style="list-style-type: none"> • Accreditation hosting (Core) • Enhanced Review Delivery (Optional) • Review Administration (Optional) 	Accreditation Reporting & Analytics (Core+) <ul style="list-style-type: none"> • Review Backlog Status Reporting (Core) • Live Accreditation Reporting (Core) • Bespoke Reporting (Optional) 	Accreditation Support <ul style="list-style-type: none"> • Review Administrator Support (Core) • Client Assessor Support (Core) • Product Owner/Applicant Support (Optional) 	Digital Health Portal (Core - See Digital Health Portal)

The components marked 'Core' are included as part of all Review & Accreditation Services. Those components that are marked 'Optional' are elements that a Client can ask for ORCHA to support or can do themselves.

3.3.1 Accreditation Design

Designing and creating an Accreditation model and approach can be a daunting task. The huge array of standards (regulatory and none regulatory) that impact and affect Digital Health solutions, as well as a number of key assessment areas where there are in reality very few useful standards or established guidance/best practice models, means that crafting a sensible, robust but proportionate and pragmatic framework is a challenge.

ORCHA has considerable experience and expertise in this area, through both the work we have done over the last 5 years on our own Review methodologies, as well as the support we have provided to a wide range of 'accrediting bodies' at national and regional levels.

We have an unrivalled overview of all the relevant standards (current and emerging) in this fast-changing environment. We also have a unique insight into all of the current assessment models that have emerged globally to date. ORCHA are also continuously undertaking research and development on new assessment components to fill known assessment gaps.

We have as part of this developed the ORCHA Accreditation Development Model that embeds all of this learning into a consistent series of tools and processes to support the accreditation development journey. Our team of Digital Health experts can provide

accrediting bodies with a range of support through this model in the design and creation of their individual Accreditation model, taking account of this wider landscape alongside the specific needs of that organisation and the populations it supports.

In practice the Design component and the Build and Test component often overlap as our Model takes an iterative approach and we build early 'drafts' of the Accreditation Model into the Review Engine's (see below) 'sandpit' environment. This enables early iterations to be 'spun up' and tested with relevant sample sets of Digital Health products, to gauge and calibrate the outcome of each version. This is a valuable way of bringing key decisions about thresholds and scoring to life and also supports a consultative approach to the Models development.

The Design component is also not simply about designing the Accreditation Model, which is in its own right made up of a number of distinct elements, but it also encompasses the design of the overall Accreditation Process that wraps around that Model. The key elements are listed below:

- **Accreditation Content Design** – what areas of investigation are to be included in the Accreditation Model and how is it to be structured? This is where the ORCHA Layering and Review componentisation allows for the rapid development of Accreditation Content. However, as the Design process is inevitably about ensuring a wide range of stakeholders are bought in to the ultimate Model, the ability to rapidly build and iterate from these core components is crucial. Review efficiency is also an important element in the Content discussion and ensuring as far as possible that the Model does not place unnecessary practical burdens on the Accreditation team or the applicant Product Owner is crucial. The Review Engine can accommodate a wide array of question and answer styles and approaches and has a significant database of 'common' answer sources from the OBR and the Enhanced Review Components to streamline the overall processes.
- **Scoring Logic Design** – what are the implications of the findings from the investigations undertaken? This can be one of the most complex areas in the development of any Accreditation Model and it is the element where each Accrediting Body has to make a judgement about where they wish to 'place the bar'. ORCHA's scoring model can be adapted to support this process or an entirely independent approach can be taken with simple pass/fail thresholds developed. Other models include a combination of approaches with many adopting the OBR scoring as an initial 'gateway' requirement and then building pass/fail thresholds in at the Enhanced or Client Review component level.
- **Accreditation Process Design** – how will the Accreditation work in practice? What will instigate the process? What checkpoints and gateways are there in the process? What is the re-accreditation approach where products or regulation change? This element is crucial to ensuring that the Accreditation is practically deliverable and sustainable. This is in practice often where most Accreditation initiatives breakdown. However the unique capabilities of the Review Engine take most of the practical pain away from Accrediting bodies as virtually all the

key 'process' and workflow requirements have been built into the system. In this stage of the Design process therefore, Accrediting Bodies are in essence configuring the Review Engine to meet their specific needs. This includes elements such as:

- Designing how a Product gets into the process – is it an application model that requires a 'front end' application portal or is it a proactive selection approach by the Accrediting body. This element links with the wider issues around Product Owner engagement and how much is required to complete the Accreditation and how this is to be managed;
- Designing the stages and checkpoints in the process and identifying what individuals or roles need to be involved at each stage. This could include initial checkpoints at the OBR stage of the process or final sign-off processes. The Review Engine supports all these elements and automatically manages the workflow according to the final construct;
- Designing who is responsible for each element of the Accreditation itself. Clients can manage most aspects of the Enhanced Review and all aspects of the Client Review components themselves using their own 'Client Assessors'. In this scenario ORCHA's involvement in the day to day Accreditation delivery is minimal and restricted to the provision of the Review Engine and the underpinning OBR data and standard support. Some Enhanced Review components can only be provided by ORCHA and in these circumstances this will be automatically built into the workflow. ORCHA can of course also support more or all aspects of the Enhanced and Client Review Components if required (see further below). The Design stage is where these critical decisions can be debated and the availability of Client Assessors analysed.
- Designing the communications associated with the Process. This is critical where Product Owner engagement is key and can be a huge source of 'Accreditation admin' if not managed intelligently. The Review Engine can deliver tailored communications via email/sms and also via My ORCHA 'Developer' Accounts, that keep Product Owners fully informed of the progress and status of their application. These communications can also be configured to ensure Accrediting Body key actors and stakeholders are also kept automatically updated and are brought into the Accreditation only at the relevant points. This is again managed via either email/sms channels or via the My ORCHA 'Assessor' or 'Administrator' Accounts.
- Designing the Re-Accreditation Protocol. This is also a key aspect of the overall Accreditation Process and is again an area that often causes considerable difficulties. For Clients using the Review Engine, much of the Re-Accreditation burden is managed through the ongoing market surveillance and monitoring features and the automatic re-review at the OBR level. This process enables changes in 'Accredited Products' to be triaged and only those that appear to involve a material change that might impact an Enhanced Review or Client Review component are pushed back into the Accreditation process for Re-Accreditation. The 'Front-end' implications of this change cycle are all

managed automatically between the Review Engine and the relevant Digital Health Portal/API connector, so that any users relying on the Accreditation outcomes can be fully informed if a specific Product is undergoing Re-Accreditation.

Where Re-Accreditation is driven by a required update to the Accreditation Model itself (for example where there is a major regulatory change to factor in), the Review Engine has again been designed to streamline updates and the creation and testing of new versions of an Accreditation Model as well as to automatically detect impacted Accredited products that then require Re-Accreditation. The movement between versions of a Model can be complex and the Review Engine supports all aspects of this to minimise the disruption it causes. The Design of all these elements is a key part of the overall Design process.

All these Design elements can be supported by ORCHA and the size of that support will depend on the circumstances and how far developed the Clients thinking or processes already are. Clients who are confident that they have all of these elements in hand can move directly to the Build and Test stage but will be required to complete a full Accreditation Model and Process Design pack that provides all the required details to support the Build and Test stage.

3.3.2 Review/Accreditation Build & Test

All ORCHA Reviews are managed and delivered via the ORCHA Review Engine (“**Review Engine**”). The primary function of the Review Engine is the ability to create, edit and manage Review/Accreditation processes. The Review Engine is a unique system that allows for the rapid development and delivery of accreditation models and processes as well as their ongoing iteration and evolution. It encompasses many components that support all the aspects of these processes and makes the techniques and tools that are used by ORCHA’s professional review team, available to our Client Assessors.

The Review Builder is a component of the Review Engine and enables ORCHA to rapidly compile a Clients preferred Review/Accreditation approach. It provides an intuitive, flexible process of development, enabling client organisations to rapidly turn the Accreditation Model and Process Design into a reality. In practice as noted above, the Design and Build components often overlap as the Design process can be iterative and the Review Engine does allow for the creation of test versions of an Accreditation in the ‘Sand Box’ environment. Some of the key features and configurable options the Review Engine supports include:

- select the overall Assessment structure and process;

- select their Assessment Questions from our comprehensive Question Bank containing all the current assessment questions utilised by the major emerging accreditation regimes;
- select and edit relevant answer types and sources
- select and group relevant Assessment sections/headings;
- import and adjust the associated question logic that ensures that Assessments; dynamically respond to incremental Assessor inputs;
- select and adjust a suitable scoring model/assessment criteria;
- select a queue logic/source for applicant solutions;
- select/assign Assessors or Assessor teams to undertake all or certain aspects of the review; and
- manage the process of creating new versions of a Review/Accreditation and all the 'change' management implications that arise from this.

The Review Engine also manages all aspects of accreditation process testing and associated iteration.

In the Build and Test stage, the designated ORCHA Review Lead will work with the Clients Accreditation Model and Process Design to establish this in the Clients own Review Tenancy within the Review Engine. The Review Tenancy is a segregated environment that can only be accessed by approved users as defined by the Client. The creation of the Review Tenancy also enables the subsequent tailoring of all elements of the Accreditation including communications and the 'Front-End' design.

A new Accreditation Model and Process can be established in a matter of weeks if the Design is fully developed. Typically where we combine the Design and the Build and Test components, this is usually a 2-3 month process.

3.3.3 Review/Accreditation Delivery and Management

Having built the Accreditation Model and Process into the Review Engine and thoroughly tested it, the process is ready to 'Go Live'. At this stage the Process Design elements are key. In practical terms the Review Engine will manage all aspects of the agreed Process and automatically manage agreed workflows and communications. The key Delivery activities that need to be factored in, include:

- Applicant/Product Owner Management
- Enhanced/Client Review Component Delivery
- Exception Management
- Change Control
- User Support (see below)
- Reporting and Analytics

The key aspects of all these elements will have been developed in the Design stage or delivered as part of the Accreditation Model and Process Design Pack. ORCHA's involvement can be very minimal in the Delivery stage and simply involve the maintenance of the Review Engine and the underpinning Data Sets and the delivery of Reporting and User Support, or it can involve more active support around Accreditation Administration, Applicant Management and Enhanced/Client Review Component Delivery.

3.3.3.1 Core/Minimum Delivery Services

The Review Engine License and ORCHA Platform Fee which cover the Review and Accreditation Service include the core Delivery components as follows:

- Hosting, maintenance and management of the Review Engine
- Maintenance and delivery of the OBR Data set
- Delivery of the market surveillance and Re-Review process
- Delivery of the unique Client Review Tenancy and related features
- Delivery of the Accreditation API
- Appointment of a dedicated Review Lead to support technical aspects of the Accreditation Delivery and change
- On-Boarding and training (e-learning and webinar based) support for Accreditation Administrators and Client Assessors (as part of Implementation Support)
- Support for an annual Accreditation Update
- E-Ticketing and Telephony support for Accreditation Administrators, Client Assessors and Applicant Product Owners (as part of User Support)

- Dedicated account management for key Client contacts (as part of User Support)
- Standard Accreditation Reporting and Analytics - All Accreditations within the ORCHA Review Engine are supported with standard Reporting and Analytics components that can be accessed by Client Administrators via their My ORCHA Accounts. This includes reports and analytical dashboards showing the overall status of the relevant Accreditation and products within it, as well as drill down views on specific aspects of the Accreditation itself. These reports and analytics enable a Client 'Accreditation' Administrator to manage all aspects of the Accreditation and to easily provide regular reports on the overall progress and outputs.

There is also the opportunity for Clients to work with our analytics and data team to create bespoke reporting or analytics elements as part of the Accreditation Design process.

3.3.3.2 Optional/Additional Delivery Services

- Enhanced/Client Review Component Delivery/Re-Accreditation support - As noted above, some Enhanced Review Components have to be delivered by ORCHA as they are driven by data sets and analysis that is unique to the ORCHA system. Most other elements can be delivered by Client Assessors using the same or adapted review methodologies. In each case the review is conducted within and managed by the Review Engine.

ORCHA's extensive and uniquely experienced Review Team are well placed to deliver any Enhanced/Client Review Component dependent upon the Clients requirements. This can be organised in a phased manner, with the ORCHA Team being responsible for an initial Assessment phase that is then handed over (figuratively) to 'Client Assessors' for the second or subsequent phases. An alternative is that the ORCHA Team act as Lead Reviewers and manage all the core elements of the Review/Accreditation, with Client Assessors being limited to specialist areas or 'sign off' of the process.

The ORCHA Review Team are uniquely placed to provide very effective support to any such Review/Accreditation process. They have collectively reviewed thousands of Digital Health solutions and are true experts in the assessment of these products and services. The team also include a range of experts who can deliver specific more technical or professionally demanding elements of a Review. This aspect of Delivery is typically charged on a per review basis.

- Accreditation Administration/Applicant Management – The organisation and administration of an Accreditation Process can be time consuming and complex. Applicant engagement and management can be a major element in this and maintaining clear and consistent communications with Applicant Product Owners around the progress and status of their 'application' is critical. Managing both successful and unsuccessful applicants is also important. Other administrative elements to factor in involve the management of Assessors and subject matter experts as well as the organisation of relevant forums and governance checkpoints for things like 'Sign Off' or Audit or exception or change management.

Whilst the Review Engine takes a lot of the strain in this area, there are still aspects of this overall administration that requires human interaction and oversight. ORCHA can provide as

much or as little support in this regard as is required. This element is usually charged on an annual managed service fee basis.

Note: The standard Review Engine License and ORCHA Platform Fee include all the OBR data set and there is no restriction on its use within the Accreditation process. There are restrictions on what elements of this data set can be made available on any 'front-end' on a free to view basis.

The standard License and Platform Fee does not include any Enhanced Review data which is typically incorporated as part of the Optional, additional Delivery services. These are usually charged on a per review basis but the unit cost for each component for each review will reduce depending on the guaranteed level of Accreditations undertaken annually.

3.3.4 Digital Health Portal Development and Management

As noted below, an integral part of the overall Digital Health eco-system is the mechanism for publishing and disseminating the results of any Review/Accreditation process. It is crucial that this is delivered in a user friendly, intuitive fashion to support relevant patient/public groups to access and assess the outputs of these processes and that health and care professionals similarly have a tool to access, assess and action (i.e. recommend/prescribe), these outputs.

It is also equally crucial that the outward delivery vehicle for all these things is also capable of providing automated updates triggered by new versions or upgrades to 'reviewed solutions' or Re-Reviews of those solutions, to ensure that the core repository constantly remains up to date and authoritative.

The ORCHA Digital Health Portal, together with the integrated ORCHA Pro-Solutions (all detailed below) offers the full end to end delivery model that ensures that the Review/Accreditation processes (initial and Re-Reviews/market surveillance monitoring) are always accurately reflected on the relevant public/clinician facing sites.

All Clients purchasing the Review and Accreditation Services will automatically be required to purchase at least one instance of the Digital Health Portal (or API connector).

The API that feeds any Front-End is part of the ORCHA Platform Fee alongside the underpinning OBR and other Data sets. The Review Engine License fee is calculated as a percentage of the overall Platform Fee as detailed in the pricing section.

The Digital Health Portal or API connector is a per instance fee.

Major National or Regional Implementations

All the fees relating to the Review and Accreditation Development and Delivery Service can be developed into a bespoke solution for major national or regional implementations. In particular ORCHA can support national or regional bodies with commercial models that distribute the overall costs of these solutions across the wider system ensuring that local and specialist providers and the developer community all contribute to the ultimate cost of delivering a fully integrated Digital Health management solution within a relevant system.

This can include:

- The levying of reasonable Accreditation Fees on applicant Developers to support the accreditation process
- The sharing of the platform fees across all participating partners within a system through the use of discounted microsite fees
- The reimbursement or sharing of revenue earned through the adoption by local/specialist parts of the system of Microsite variants and related fees.

3.3.5 Review and Accreditation Implementation Support

As summarized above, all Review and Accreditation services include a basic Implementation Support approach. Each Client Review is assigned an ORCHA Review Team lead to act as the key liaison point between the Client Review team and the ORCHA Review team. The ORCHA Review Team lead will provide advice and guidance for up to the time specified in the pricing model (which is dependant upon the Review Engine Licence purchased).

The ORCHA Review Team lead will also be responsible for the build of any Client Review within the Review Engine and an allowance for this will be taken out of the overall implementation support days provided.

For Clients adopting the more substantive Accreditation Design and Development support module, this will replace the basic Implementation Support described above. This will still however involve the appointment of an ORCHA Review Team lead and will include the build of the Client Review in the Review Engine.

Any Client Digital Health Portal Implementation will be supported as detailed in the relevant section below.

3.3.6 Review and Accreditation User Support

ORCHA operate 4 levels of user support. This includes:

- Online support tools, FAQ's and 'how to' resources
- e-ticket support
- telephony/web chat support
- Key account management

For our Review and Accreditation support we offer the following:

User Type	Support
All	Online support tools
All	e-ticketing
Client Administrators, Assessors and Applicants	telephony/web chat
Client Administrators/Key Account Contacts	direct account management

The relevant response and resolution KPI's for each support element can be found in section 7. The key account management in the Review and Accreditation service includes ongoing access to the designated ORCHA Review Team lead throughout the duration of any agreement for the time specified in the relevant Client Agreement.

4 ORCHA Digital Health Portals (Libraries, Catalogues and Formularies)

4.1 Background

If establishing a clear and robust Accreditation process to support the target use case (or use cases) is a first key step to driving and accelerating the uptake of Digital Health, the next steps are all about engagement and activation of relevant stakeholders through the publication and dissemination of the results of the Accreditations in formats that are tailored to meet the differing stakeholder group challenges.

Whilst creating a 'front-end' repository of 'approved' Digital Health solutions in the form of a Digital Health 'Library' or Catalogue is an integral and necessary part of an effective Accreditation process (supporting elements such as 'the closed loop' approach and obviously providing a platform for Developers to showcase their 'approved solutions' in return for their participation), the nature of this 'front-end' solution and how and what it delivers needs to be carefully considered as part of an overall transformation programme.

4.1.1 Distinct End User Groups

Digital Health 'Libraries' will (or could) have a number of distinct audiences who will require different things from it. The obvious end audience are patients and the wider public. For this group the Library needs to deliver an intuitive and engaging 'user experience' that makes the task of searching for and finding Digital Health solutions that will help them as easy as possible. The level of information that needs to be surfaced from the accreditation process itself is therefore typically more limited and also needs to be provided in a format that is none technical and easy to understand.

The rationale for this groups direct engagement with such a Library is all about delivering direct population activation. This is a legitimate aim, but considerably more is needed to be done to really drive public awareness of and engagement with such a solution and simply making a Library available is not likely to deliver much tangible activation in and of itself. What is needed is a much more considered population activation strategy that leverages all of the assets that most health and care systems have at their disposal. This is likely to include a 'localisation' component with the creation of multiple local versions and variants of the national Library that can be targeted directly to smaller population groups and patient cohorts by the local organisations who are 'on the ground'. We have detailed this further below.

The other most obvious audience are the health and care organisations and the professionals that work within them in that national or regional geography. For this

audience the aim is not necessarily to drive use directly (although this is in and of itself not a bad strategy to support professional engagement), but to try to activate this cohort to embed the use of these solutions into their day to day work and drive uptake within their specific populations and patient groups. Unleashing the power of the professional community and having this group be one of the major activation agents is the key to accelerating the uptake and adoption of Digital Health in the most relevant sections of a population.

The requirements of this professional community from the 'Library' are likely as a consequence of this focus, to be very different to their patients or service users requirements. This group are more used to 'formularies' and to tools that guide them to 'therapeutic' options in a structured way that is already well established and familiar. The information requirements and the corresponding pull through of data from the relevant Accreditation process is also likely to be very different for this group. We have seen that for many professionals they will take the time to look in more detail at a solutions credentials and for clinicians in particular there will be a big focus on Clinical/Professional Assurance data and compliance.

National v Local Libraries

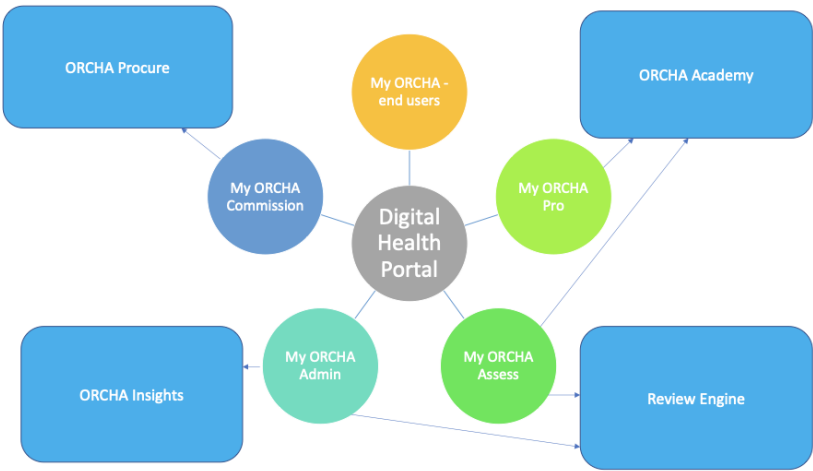
The ORCHA (Digital Health) Transformation Model detailed below, envisages - based on our experience to date - that even where a national or regional Library exists, local organisations will typically configure their own variant of this to reflect the micro-implementation and associated micro-assessment processes that they will typically undertake. The local Library's 'public facing' elements may well be very similar to the national Library (albeit the content and products showcased is likely to be tailored to the population needs of that specific organisation (mental health, cancer etc)), however the internal 'Formulary' version is much more likely to be based around the results of the Micro-Implementation and Assessment model (outlined below) and within that each individual team or department is likely to have a specifically tailored 'front-end' that reflects this.

Any front-end 'Library' that supports a given accreditation process thus needs to be capable of delivering these (and a wide array of other) 'user experiences' if it is to successfully support these key stakeholder groups. The ORCHA Digital Health Portals offer a huge level of configuration to accommodate all of these needs. Role based access enables different levels of information and different search structures to be accommodated depending on who is viewing the sites. The Portals are of course tailored to accommodate the outputs of any given Accreditation and Accrediting bodies have a lot of options in terms of site look and feel and content.

4.2 Digital Health Portals Service Components

The ORCHA Digital Health Portal or Library is the component of the ORCHA overall product suite that is focussed on the publication and promotion or dissemination of any approved Digital Health solutions and also the component that sits at the heart of population and professional activation strategies.

The Portals are also however the hub for many of the other ORCHA products and services including ORCHA Pro-Solutions and Client Review and Accreditation Services. The My ORCHA account feature described below, is the entry point to these other services for Professionals, Client Assessors and Client Administrators accessing all the other services.



The Digital Health Portal is therefore an integral part of most of these services and is a required element in the delivery of many.

The following table illustrates the Service Components within the Digital Health Portal.

Digital Health Portal						
Content Curation (Core)	User Views & Controls (Core)	White Labelling & Configuration (Core)	My ORCHA (Core+)	Campaign Support (Optional)	Performance Reporting (Core)	Implementation Support (Core+)

The components marked as Core are included within the core Digital Health Portal pricing. The components marked as Core+ have elements that are within the core but also elements that can be added on as optional additions. Components marked as Optional are available as required but will attract additional costs.

4.2.1 Content and Curation

The content for any Client Digital Health Portal can be selected and tailored to meet the specific needs and requirements of the relevant target population. The selection of this content and the augmentation of it through local micro-assessment/accreditation processes are a key element of the ORCHA Digital Health Transformation Model outlined below. The process of evaluating what specific solutions (from the ORCHA 'master library') best fit the specific needs and situation in question is in its own right a hugely powerful transformational process and significantly supports the adoption and engagement challenge that will be found in most traditional care settings.

The core element of the Portals therefore is the publication of the 'curated' content that flows from the Accreditation process/s that underpins it. The content curation is highly flexible and although the primary content (certainly at a national and regional level) is very much the Digital Health solutions that have been through a particular Accreditation process, it is possible to mix and match and surface content from different layers of assessment (such as the OBR) alongside 'approved content', in given circumstances and for specific audiences. For example it is quite common for Local, public facing Libraries to provide both OBR and Locally Approved content, with the latter always being promoted and highlighted on specific searches over the former. This allows organisations to allow end users a wider degree of choice - outside of the smaller group of internally approved solutions - whilst still clearly sign-posting them to locally preferred options where they exist.

All the front-end content is derived from the Review Engine and this is API driven, allowing for even greater flexibility in what is delivered in each specific circumstance. The key API's include:

- 'App' Characteristic Data (Part of the OBR Data set)
- OBR Compliance Data (Part of the OBR Data set)
- ERC Data
- CRC Data

As most accreditation processes will be made up of elements of each of these Data sets the Portals will be supported by elements of all of these. In the case of Client Review

Components (CRC's), part of the design and delivery of these within the Accreditation development stage relates to the outward manifestation of that CRC output and this can take many forms and be built into the 'front-end' in a range of different ways to reflect specific requirements.

4.2.2 User Views and Controls

All Portals can be delivered with a 'free to view' option or a registration 'firewall' that restricts access to registered user only. Hybrids of either of these approaches can and are often also adopted and 'professional' access for example, is always controlled via a login.

In free to view mode, the end users experience and the information provided will be the same for all. The amount of content that can be made available in free to view mode is restricted to specific aspects of the OBR data sets. There are no restrictions on CRC data.

For those accessing the Portals via a login, the user experience, the information provided and the functions and features available can be tailored to that specific individuals' requirement. Professionals logging in for example will typically encounter a distinct 'formulary' based search structure and will have access to more information on each approved solution. They will also have access to an array of additional features and functions. We refer to this distinct array of functions and features that are available to a Professional using the Portals as our Pro-Solutions and these are set out in more detail below, but they are additional to the many standard features of the Portals.

Some clients require that there is a registration and login requirement for all users. This can often be linked to existing account constructs where the Portal access is to be part of an existing membership model or is being added into an existing product set. Again, for Professionals we will always where possible look at options to link the ORCHA Pro-Accounts to existing network or system logins to deliver a single sign on solution.

4.2.3 Digital Health Finder – the Digital Health search engine

One of the most critical but often overlooked features of any effective online 'Library' is how easy it is to find the content within it. Search rapidly becomes a crucial element when the number of reviewed solutions passes even the 25-30 mark. With thousands of reviewed solutions available within the ORCHA Review Engine, effective search is essential. This is where the 'Digital Health Finder' component comes in. The Finder is all about the powerful search features that we have developed and continuously iterate and improve to maximise the chance of an end user finding a solution to meet their specific needs.

The Digital Health Finder offers a range of different search approaches. This includes simple free text search, which is constantly being optimised to limit as many no search results as possible. The other search elements are unique to the Finder and allow for more

tailored searches to be made on a range of 'characteristics' to maximise the chance of finding a solution that really delivers what is required and is suitable for the end user in question. This includes the ability to filter searches by 'Design for' i.e. children, adults professionals etc, key features and functions, paid for or free etc. In the ORCHA Pro solutions detailed below, this 'advanced search' feature has started to be molded around a formulary construct that allows professionals to look at 'indications', contra indications and also select options around the stage of a care pathway or patient/user journey that the App supports.

These search components rely initially on the users characteristics being 'input' by the individual themselves. However, integrations with patient record systems can automate elements of this, enabling the Finder to proactively scan for and propose solutions that might be suitable for the individual concerned. This feature can be augmented using the 'profile building' elements of the My [ORCHA] account features detailed below.

The Digital Health Portal/Library and Finder have a wide array of configurable components to support clients to meet their own specific requirements and challenges and to really target the audience they want to activate or support.

4.2.4 Portal Design and Configuration

The Client can adjust the standard configuration of their App Finder up to 4 times per Annum. The Portal standard configurations include:

- **'White labelling options'**

These include the adoption of a relevant theme and associated look and feel, a choice of imagery, the incorporation of client logos and a client specific About Page.

- **App Library filters**

These include the selection of minimum scores, specific focus categories, features/functions, country of origin, free/paid for, designed for/PEGI rating options, and specific compliance elements.

- **Search Results priorities**

Portal Owners can choose the basis on which search results are presented including: Nationally Accredited, Locally preferred, or score order,

Supported jurisdictions/languages can ensure only Apps available in a relevant jurisdiction and or in a relevant language are displayed.

The following customisable features are available as part of a standard build:

- **The selection and set-up of a suitable site theme and imagery**

This allows Clients to start to align their Library to their branding guidelines and/or the target audience in mind. There are currently 8 available pre-selections. Clients can also choose from a large bank of imagery for their site look and feel or provide their own imagery for inclusion.

- **The selection and set-up of a number of standard display templates.**

These templates allow Clients to select what elements of either the OBR or their own Review/Accreditation they wish to make available to their audience.

- **The selection and establishment of an agreed URL**

Clients can select from a standard [Client name].orcha.co.uk approach, or purchase their own unique url i.e. [Client name]healthapps.co.uk or .nhs.uk etc, that we will redirect the .orcha site to.

- **The selection of the agreed Digital Health solutions to be displayed**

This is crucial to the overall targeting and marketing of the site. For Clients purchasing just the Portal and associated tools, the Reviews that are available are based on the OBR. This provides access to a growing Library of reviewed Digital Health solutions across the full spectrum of health and care conditions and wellness areas. The overall Library can be filtered to reflect the focus of the site and the target audience. This can be done on an 'App by App' basis or using any number of the Digital Health 'App' Characteristic data set (Condition focus, Designed For, Key features, OBR Score, Available Accreditations (i.e. NHS Approved) etc) or any combination of these. In addition, clients can pre-filter solutions to exclude those with key compliance characteristics (OBR minimum score achievement, other accreditations (i.e. NHS Approved), specific compliance with key regulations, free v paid etc). For clients that have built their own Accreditation within the Review Engine, the default publication will be the results of that Accreditation process but these can also be filtered by all the available data elements outlined and described in detail in the ORCHA Data Scheme.

- **The selection of focus areas and associated search shortcuts and promotions**

This should align to the overall theme of the site and the selection of the Reviews/Accreditations to be presented. The site offers a number of standard 'features' panels and carousel shortcuts to reinforce the focus and to aid the navigation of users to high priority areas.

- **The selection of preferred Digital Health solutions and/or search result priorities**

This feature allows Clients to define what the order of search results should be based upon. The default ordering is based on the OBR score. For Clients using the OBR they can however also 'prefer' Apps with certain characteristics such as NHS Approved Apps or Locally Preferred Apps. This will ensure that any Apps that are a key focus or are already part of the local system always come to the top of relevant searches. This really supports the embedding of 'preferred' Apps into a specific environment and is a key first step to integrating Digital Health into day to day care delivery.

- **The selection of displayed 'Assessment' content**

This feature links to the templates feature outlined above. This element is linked to Clients own Reviews/Accreditations and allows for the display of associated content from those reviews. This can include for example a Key Findings panel that is edited as part of the Client Accreditation process within the Review Engine and of course will include the relevant 'scoring' approach and associated content.

- **The selection of User Registration options**

The Library comes with a My [ORCHA] account feature that can be enabled or disabled as required. The primary benefits of the account feature is to allow the use of 'role based' access, automatically adjusting the content, functions and features for a specific user group (i.e. Professionals). In addition, the My [ORCHA] account also allows the ability to understand better the usage profile of those using the site. This feature can also be used to restrict access to certain user groups i.e. patients, members or employees. The benefit to the registering user (other than where it is an access device) can be the creation of 'suggested' app prompts based on their usage or their stated preferences/interests. This feature can also be used to alert users who have downloaded a Digital Health 'App' to major changes in it and any major degradation of the Apps score. This can also of course flag an Apps move from an Approved status to an unapproved status following a Re-Accreditation or new Accreditation version upgrade.

4.2.5 My ORCHA

As noted above the Digital Health Portal also includes a My ORCHA account feature for end users (and ORCHA Pro users if applicable). The My ORCHA Account for end users supports the delivery of alerts to Users around changes to any products they have downloaded and also alerts regarding new products in the same category and condition areas (both are of course subject to specific opt ins). The My ORCHA Account also supports the 'Leave a Review' feature that allows us to source feedback directly from end users about the

efficacy of the product. This in turn supports upstream enrichment of the User Experience evaluation. The My ORCHA account feature can be enabled or disabled.

4.2.6 Portal Promotion and Campaign Support

As noted above, where one of the aims of the Portal is to promote Digital Health directly to an end user (public) population this needs to be developed as a fully considered promotion and activation campaign. Simply making a Library available is unlikely to generate much interaction without the use of a range of more sophisticated promotional approaches. Where the strategy is to target specific groups within a population this 'campaign' element is ideally developed during each micro-implementation phase described in the ORCHA Transformation Model.

Whether or not the target group is generic or specific, there are a number of promotional and activation strategies that can be adopted. Some of these include:

- **Digital Healthy Schools deployment**

The Digital Healthy Schools (DHS) approach provides Digital Health Libraries for local schools to deploy and promote to their students/pupils and the wider school community. This is all done via an automated solution that allows schools to set-up their own satellite Portal sites based on a relevant regional or local 'master' Portal. The DHS service comes with a range of tools and resources for schools to use to run PSHE lessons on Digital Health to further embed the activation impact. The schools are also able to use the service to create the equivalent of 'Pro-Accounts' for Teachers and Student Services and Welfare teams who are able to 'recommend' Digital Health solutions to specific pupils. The DHS model also enables pupils to recommend solutions to friends and family and this is designed to deliver a 'digital champions' effect via the pupil groups into the wider community. A DHS deployment can thus form an effective and powerful population activation strategy.

- **Health and Social Care staff deployments**

Creating or promoting a Portal to health and care staff has two benefits. Firstly, driving the adoption of Digital Health solutions within this key group should aid with overall sickness and absence rates. Secondly, by promoting to this key group, this will aid the overall activation of health and care professionals supporting the Pro-Solutions deployment process.

- **Existing digital asset links**

Connecting local health and care system websites, social media forums etc, to the Library can ensure that users of each of these varying resources can access reviewed digital health tools from their own trusted source.

- **The use of e-promotions via patient or service user lists using existing sms/e-comms solutions**

This can be managed in a number of ways and is very much a hybrid approach to Pro-recommendation with recommendations being generated to relevant cohorts or individuals based on their specific characteristics.

- **The creation of Digital Health surgeries/drop-in sessions in suitable local environments/forums**

These 'outreach' approaches can be targeted at a wide range of different locations and forums to support the specific aims of the programme.

- **Social Media campaigns**

Social Media campaigns can be effective in targeted approaches.

- **Posters, flyers and cards for deployment in relevant settings.**

Each of these elements is independent of health and care professional promotion approaches and formal recommendation and prescribing strategies dealt with further below and which also form a key element of the ORCHA Transformation Model micro-implementation approach.

To support these approaches, we have developed a wide range of assets and 'campaign' models that can be easily adopted for each implementation phase.

Clients can specify as part of an Augmented Implementation Support service, which elements of these Portal Promotion techniques they wish to adopt and/or have supported. The pricing implications for each are detailed in the pricing section.

4.2.7 Performance Reporting

The monthly performance monitoring and management reporting will provide data on all aspects of the Digital Health Portal and Pro Solutions' (where applicable) use. This is

accessed via the My ORCHA Admin Account features. All aspects of Portal promotion and campaigns reporting are also delivered through this function.

This reporting can form the basis of an overall programme evaluation, but this solution can provide additional evaluation components to deliver a more advanced assessment of the impact of the solutions using a range of evaluation methodologies including Patient Activation Measures, GAD scores etc.

The core Performance Reporting dashboards and reports are included in the relevant Portal Fees described in the pricing summary

4.3 Digital Health Portal Implementation Support

Each Tailored Digital Health Portal License comes with a bundled support package. The package includes:

- Set-up and configuration support,
- Initial familiarisation and training sessions,
- Initial campaign development and support,
- Ongoing performance management and reporting as well as user support and maintenance.

This support is usually delivered through the initial 3 months of an Implementation and is both on the ground and remote support including:

- Portal set-up and configuration,
- General training and familiarisation support,
- Event support and stakeholder management and activation,
- Digital campaign asset co-ordination and management.

The Implementation Support is tailored to each deployment and is based on the estimated effort dependent on the specific product configuration, geography and use cases.

For Clients purchasing the ORCHA Transformation Model, this will in effect replace the standard Implementation Support approach and provide the augmented and highly structured support package outlined in that Service Component.

4.4 Digital Health Portal User Support

ORCHA operate 4 levels of user support. This includes:

- Online support tools, FAQ's and 'how to' resources
- e-ticket support
- telephony/web chat support
- Key account management

For our Review and Accreditation support we offer the following:

User Type	Support
All	Online support tools
All	e-ticketing
Client Administrators	telephony/web chat
Client Administrators/Key Account Contacts	direct account management

The relevant response and resolution KPI's for each support element can be found in Section 7. The key account management in the Review and Accreditation service includes ongoing access to the designated ORCHA Review Team lead throughout the duration of any agreement for the time specified in the relevant Client Agreement.

5 ORCHA Pro Solutions

5.1 Background

The ORCHA Pro-Solutions works in concert with the Digital Health Portal and the Review Engine. The ORCHA Digital Health Portals include a series of specific enhanced functions and features for health and care Professionals that we refer to as the Pro-Solutions suite. The Pro-Solutions leverage the core functionality of the Portal in terms of content curation, search and user views and access controls but orchestrate these in a manner that is tailored to the specific needs of this Professional group. The Pro-Solutions also build on the core functions of the Portal and Review Engine to provide a full end to end management solution for organisations looking to properly integrate Digital health into their day to day practices.

The act of recommending a Digital health product through the Pro-Account features is a key tool in the activation journey. Proportionately, individuals are over 10 times more likely to respond positively to a prompt from their clinician or other health or care professional than if they arrived on the site as a result of a direct search, website referral or social media campaign. Engaging and 'activating' professional communities is a core feature of our solution. This is an area in which we - with over 3000 registered professionals already on board - have unrivalled knowledge and experience.

The ORCHA Pro Accounts are at the heart of the ORCHA Pro solutions. The key feature of the Pro Account is the ability for a health and care professional to recommend specific Digital Health products to an individual. This is a hugely effective method of incorporating digital health solutions into the health and care system.

The advantages of encouraging this route are:

- The activation effect of a Pro Recommendation is significant with over 60% of recipients responding positively to this,
- The targeting that health and care professionals can deliver to the hardest to reach but highest priority users is second to none.

All transactions undertaken via the Pro-Account are logged within the Account and form a crucial audit trail of the interaction that can be built into wider clinical systems records. This also establishes the key chain of indemnity from the Professional to ORCHA and ultimately to the Developers themselves.

In addition, the ORCHA Pro Account is the foundation for the support of a Digital Health 'prescribing' solution with the Pro-Accounts allowing commissioners and payers to track what solutions have been recommended/prescribed and which ones have been actioned by the end users.

The Pro-Accounts also provide a raft of other information around 'digital activation' amongst professional communities.

5.2 Pro-Solutions Service Components



The components marked as Core are included within the core Pro-Solutions pricing. The components marked as Core+ have elements that are within the core but also elements that can be added on as optional additions. Components marked as Optional are available as required but will attract additional costs.

5.2.1 The ORCHA (Digital Health) Transformation Model ("OTM")

Whilst the publication and promotion of the outputs of an applicable accreditation process is a key element of any effective accreditation model, to truly drive adoption and integration of the evaluated solutions requires the active engagement of front line bodies/providers and the localisation/tailoring of the national/regional solutions is a crucial to delivering this.

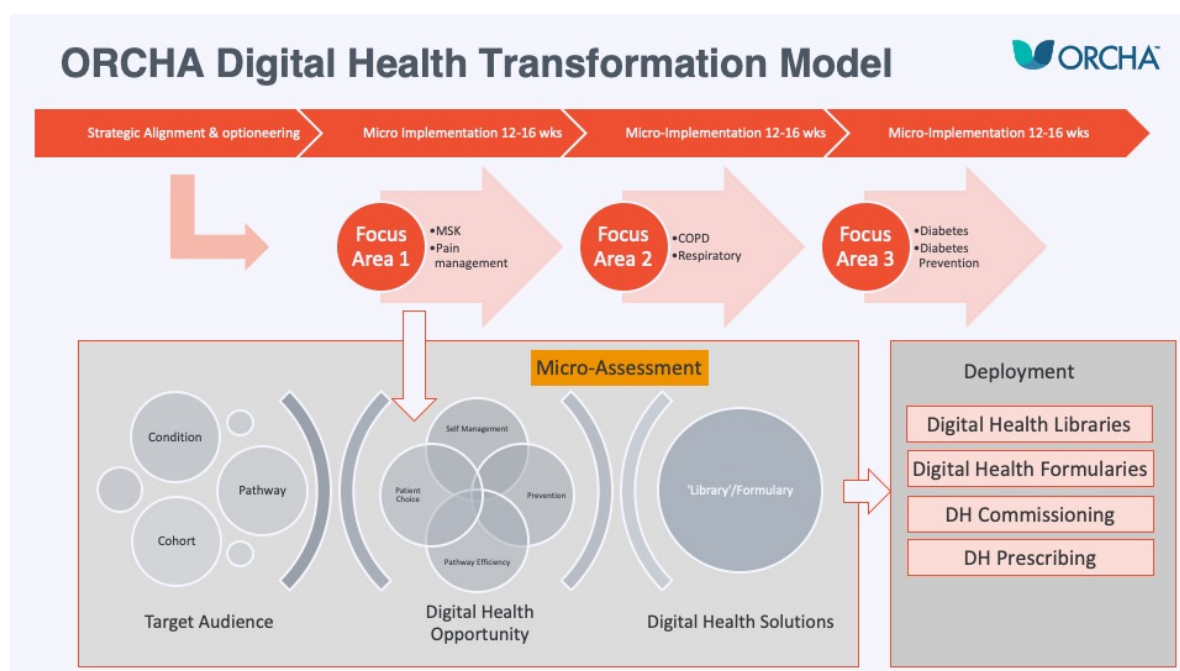
It is of course possible - and in most systems advisable - to link these two elements, both elements are needed to truly deliver the integration required.

At a local level, the challenge is therefore all about delivering effective transformational change within current working practices and procedures in order to truly embed Digital

Health solutions and to ultimately drive uptake and use within their target populations. Having a foundation of accredited solutions to leverage is just the starting point for this and there are many other elements that are needed to support the delivery of this as an effective programme of change.

The ORCHA Digital Health Transformation Model has been developed over multiple engagements with a myriad array of health care providers and systems and brings together the lessons learnt from all these programmes. The model includes a suggested Implementation Approach which outlines the key steps to take in undertaking a Digital Health Transformation Programme and this links the implementation of the relevant ORCHA solutions with a broader change and project management process.

The model is focussed on the integration and adoption end of the process at a local level. It can however easily be adapted to support a system wide approach and as part of that the development of the relevant 'Accreditation' solution for that system would be an initial phase pre any local implementations.



The OTM Elements

- Accreditation development

As noted above, for a system wide (local, regional or national) programme or where there is no obvious alternative accreditation model to leverage, developing this is a key first step to ensure that there is a suitably trusted selection of solutions to push into the local 'on the ground' activities. The delivery phase of the overall accreditation cycle would in this scenario naturally be phased to align with the Micro-Implementation phases referred to below.

- **Strategic Alignment**

It is clearly advantageous to align the integration of Digital Health solutions as far as possible with ongoing initiatives or areas of focus. In many ways Digital Health should be seen as a cross cutting initiative that has a potential role to play in all parts of the system and in all elements of system/pathway re-design.

- **A rolling programme (Micro-Implementations)**

As Digital Health can and should ultimately support virtually all areas of health and care delivery it is sensible to take a phased approach to its introduction and to develop a rolling programme that tackles key condition/pathway/cohort areas in turn. This allows for a much more focussed and structured implementation process. Within each of these phases the critical tasks include:

- Identify the target audience
- Identify the potential service improvements that Digital can drive
- Identify the potential ROI and associated key performance indicators
- Select relevant Digital Health products and solutions that can best deliver the target benefits
Agree a 'campaign' strategy to reach the relevant target audience and to activate the relevant Professionals
- Consider which solutions require commissioning (i.e. should be 'prescribed') and which solutions require 'data' integration.

Assessing each of these elements in each 'micro implementation' phase ensures that the right target audience, the right solution fit and the right promotion and activation strategy are identified for each target group or area. In the initial phase this will in practice mean a relatively small number of Digital Health solutions are selected in order to ease the integration of these new 'therapeutics' into working practices and to start to make their use 'habitual' amongst key professional groups. Over time however, it is envisaged that additional solutions will be added to the initial set as confidence in their use grows and new use cases emerge.

This is essentially the process that supports the creation of a Digital Health formulary and we envisage that this will grow area by area over time and will then be added to as new solutions and new use cases are identified in already 'activated' areas.

It is the combination of this structured programme of change and ORCHA's unique tools and resources that maximise the chances of successfully accelerating the adoption and uptake of these game changing 'digital therapeutics'.

The OTM is in essence a form of augmented Implementation Support plus Review and Accreditation and the service is costed in line with those elements as detailed in the pricing summary.

5.2.2 Digital Health Commissioning

A natural outcome of the Micro-Implementation process - and the OTM generally - is the selection of bundles of Digital Health solutions that support a specific area of focus within that particular health and care system, economy, organisation or community.

These solutions will fall into two broad categories - "Prescribable" and "Non-prescribable". The former will typically be solutions that are intended to become an integral part of the model of care within any given organization or system and where uniformity and conformance on the part of both professional and patient/service user in their choice of solution is critical.

The latter solutions will conversely likely offer value and downstream benefits to the system but will in characteristic be much more 'independent' of the core health and care systems and processes and will in that sense be more akin to over the counter drugs that end users or patients choose to adopt or not.

Most "prescribable" solutions will require some form of reimbursement model and will effectively need to be commissioned or procured on behalf of the organization/s that are using them. The ORCHA process and the OTM that wraps around this, provides all the major components of a commissioning process and ORCHA can facilitate the commissioning of the selected solutions to the relevant organisations or bodies through our App Bundles approach.

This is supported by ORCHA's collaborations with a number of relevant framework providers that provide a compliant procurement route for these products and services.

This allows organisations to purchase all their Digital Health solutions ('Bundles') either directly via an applicable framework or through ORCHA as a one stop shop. What this means in simple terms is that instead of an organisation entering into multiple individual arrangements with specific Digital Health providers, they enter into one contract and set of financial arrangements with ORCHA and ORCHA manages all the downstream contractual, financial and practical (implementation and support elements) on their behalf. ORCHA are in effect building a Digital Market Place for Digital Health solutions and most of our ORCHA Developer Community are signing up to this. This enables health and care organisations to commission all their Digital Health requirements through one overarching management contract.

The fees for Digital Health commissioning are generally based on a percentage of the overall transaction cost whichever model is used. This activity based pricing model is already factored into the relevant frameworks that ORCHA support. Where ORCHA act as the Commissioning Agent or as the managing Agent for Commissioned products, this will attract a larger activity based price, to be agreed on a case by case basis.

5.2.3 Digital Health Data - integration facilitation & management

The ultimate vision for many health and care systems is the ability to integrate the data collected by Digital Health solutions into Clinical Record systems such as EPR's and PAS's. There is currently no standardized approach to delivering interoperability between Digital Health products and services and the wider clinical system environment. Whilst standards such as FHIR and HL7 are starting to make inroads in terms of the technical integration standards, related issues such as Privacy (and associated models of consent) and user authentication remain challenging. Ultimately solutions do exist to all these challenges but they are currently fragmented and no one overall approach has gained sufficient traction nationally or internationally.

One of the roles that ORCHA can perform is to broker the adoption of a common integration protocol with the growing ORCHA Developer Community in order to establish as far as possible a singular integration model on the Digital Health side of this equation. We are also working with an increasing number of major clinical system vendors to try and facilitate this on their side of the equation.

This component is usually developed as a form of enhanced Implementation Support or alternatively is integrated into the OTM support model.

5.2.4 Digital Health Formularies

The end result of the OTM process is the development of Digital Health Formularies for the organisation/s concerned and one of the key elements of the Pro-Solution is the ability to alter the content displayed to Professionals and also the ability to deliver that content via alternative search and filter options that are more intuitive to that audience.

In the latter case, this revolves around things like taxonomies and 'Library' structures that reflect existing and familiar approaches such as the British National Formulary or equivalent. In terms of Filters, these are in the Pro-Solutions geared towards 'indications' and look to mimic the logical flow of existing decision support tools in terms of identifying possible solutions. Most of these elements will in the first instance not be a major requirement as Professionals will typically only have a relatively limited set of solutions to choose from and engage with via the micro-implementation process. Overtime however as the number of solutions grows the formulary construct will become increasingly crucial. In less specialist areas such as General Practice, this will become an issue much more quickly.

The formulary construct does also allow the generation of automated analysis based on information within a relevant patient record as would be the case in other decision support systems. If it is possible to extract key patient or user characteristics from an existing record (age, gender, prior conditions, medications etc) it is possible to auto suggest solutions that might be suitable. This can also be refined by integrating further with existing EPR or PAS systems so that the auto suggest can be adjusted dependent upon the information being captured during that specific consultation. This clearly requires a degree of data integration and interoperability and will be dependent upon existing EPR/PAS system capabilities.

In addition to enhanced and tailored search and filter options, the content from an accreditation process that is made available to Professionals will be different. Typically, this would focus on the Clinical/Professional Assurance domain and enable Professionals to view in more detail the evidence provided around efficacy of impact or clinical safety. The results of any Clinical Assessment ERC can also be viewed (and indeed much of this will be built into the filter elements of the formulary in any event).

Although a key part of the ORCHA Pro-Solutions, the creation of a Formulary is a combination of the core functionality of the ORCHA Digital Health Portal and the Pro-Account (detailed below). It is therefore not priced as a distinct item but is bundled into these fees.

5.2.5 'App' Prescribing/Recommending

The most important feature of the Pro-Solutions is the prescribing/recommendation feature that delivers the key outputs and drives the ultimate outcome. This is ultimately what the formulary construct is designed to facilitate the prescribing or recommendation of Digital Health solutions to patients and service users. Whilst this is on the face of it a relatively simple function, delivering as it does an email or text based 'prescription' to a relevant individual, it is the key element to an overall Digital Health prescribing solution that enables organisations to manage the whole process of Digital Health prescribing across their system.

Prescribing a Digital Health solution is clearly different from recommending it and it is for each organisation to decide which route to adopt or when and for which solutions prescribing is appropriate. The ORCHA Transformation Model process is ultimately about supporting organisations through this and identifying the Digital Health products and services that are viewed as adding demonstrable value to existing pathways or processes. Ultimately without adopting a prescribing approach, organisations are limited to either recommending products to their patient or service users that may cost them money at the point of download or restrict the products and services in their 'Formulary' to only free options. This will in practice severely inhibit the value that can be delivered, as perhaps not surprisingly the better solutions are increasingly 'paid' for options.

It is important to stress however that whilst a prescribing approach is the ultimate goal, recommendation options are still extremely valuable and can be a legitimate stage in an organisations journey. The activation effect of recommendation is considerable with over 65% of recipients actioning the recommendation, which compares to an activation effect without Professional engagement of around 4-6%. Whether recommending or prescribing, the ability for Professionals to target and reach the specific audiences and individuals that are most valuable to digitally 'activate' is second to none and it is this combination of effects that makes the leveraging of Professional recommendation so crucial.

If a prescribing approach is ultimately adopted, it is crucial that the recipients of the prescription can then easily access the prescribed solution at no cost and that the financial 'transaction' management is catered for behind the scenes. The ORCHA Pro-Solution

enables this by providing in a number of different ways depending on the product or service in question, a free access to the relevant product for the end user whilst logging the relevant transaction in the 'back-end'. On a monthly basis this allows for the total number of transactions for each solution to be collated and appropriate financial reimbursements to be made.

Professionals can also choose to share links to App reviews rather than recommend. Professionals can choose from a range of sent from options to personalise the recommendation or sharing communications.

The Pro-Account provides a full audit trail of all these transactions and where the recipient client/patient consents, will also show whether the recommendation has been acted upon (this is managed as part of the recommendation to clients/patients process).

5.2.6 Professional Training and Development

The Pro-Account is the access point for the ORCHA Digital Health Academy. This provides professionals with a range of e-learning and webinar-based modules which cover basic introductions to Digital Health right through to more specialist elements focused on specific conditions or care pathways.

The Pro-Academy also provides access to relevant curated third-party resources that are relevant to their specific areas of interest. This will for example include access to relevant studies or trial summaries, articles on aspects of Digital Health that are relevant to their specialisms etc. The Academy also includes curated (and CPD accredited) courses that guide professionals through different levels of Digital Health proficiency and support them in gaining confidence in this new area.

In addition to learning materials the Academy also includes access to relevant forums and groups which can be tailored on a case by case basis. This allows Professionals to safely comment on or enquire about products to an audience of fellow Professionals either within their team, their organisation or within the wider ORCHA Professional Community. These wider forums are restricted to ORCHA Pro's and are monitored and curated as part of the overall Academy management.

The Academy is a crucial tool in supporting Professional activation and is key to aiding professionals to traverse the 'chasm of uncertainty' that most will face when they are first asked to engage in these new tools.

Access to the Academy content is included within the relevant Pro-Solution fees. ORCHA can provide additional or bespoke content or training on an individual case by case basis.

5.2.7 Micro-Accreditation and Clinical peer reviews

The Pro-Account is also the access point for the micro-assessment/accreditation process outlined in the OTM and summarised below:

Micro-Assessment

A key part of the whole process of Micro-Implementation is what we term 'Micro-Assessment'. This is the process of selecting the initial and subsequent solutions to engage with. Micro-Assessment is essentially a build on the adopted accreditation model (which can be either the ORCHA Baseline Review, a bespoke solution or a relevant regional or national assessment model), but crucially allows local teams and potentially patient groups to be engaged in selecting the products to use. This is a hugely beneficial process in driving adoption and 'acceptance' of the products in question, which despite the most rigorous of national or regional assessments will (in our experience) still be questioned at a local level without this final step.

The ORCHA Review Engine has been designed to make the process of 'Micro-Assessment' very effective and efficient and this seamlessly links into the overall Micro-Implementation 'rolling' programme phase of the model. In addition, the Micro-Assessment functions are then available on an ongoing basis to support the assessment of additional solutions into an existing 'Digital Health Formulary'.

All 'locally' assured products and services are also monitored and re-assessed by ORCHA in the event of any changes or upgrades as part of the closed loop process (described further below), so that local bodies can be assured that the selected products remain safe and compliant over time.

This feature enables relevant Professionals to undertake assessments as part of the agreed micro-assessment process via their Pro-Accounts.

Professionals can also be given the opportunity to 'peer' review the Clinical Leads Assessment and this automatically flows back into the Review Engine and stimulates and supports an ongoing cycle of review by that Lead based on the ongoing 'peer review' feedback. In some instances, the Clinical Assessment ERC will be conducted specifically for

the organisation in question as part of the micro-assessment process. In this instance the 'peer review' process is the same but is limited to that organisation and the feedback loop is to that organisations Clinical Lead.

The Pro-Solutions also enable Professionals to add their own more general feedback via the Pro-Review option and this is treated as a separate source of data that can be used as part of both the user experience analysis (essentially being a form of patient or user reported outcomes) or the clinical assurance side of the analysis where the focus is on safety, risk and evidence of efficacy. All Pro-Review content is structured in a consistent way across all sites to enable the aggregation of this data across the very wide and diverse ORCHA Pro-Community.

Micro-Assessment is a feature of the OTM model and attracts the applicable OTM fees set out in the pricing summary. The peer review and leave a review features are part of the core Pro-Solution fees.

5.2.8 Pro-Data and Insights

The Pro-Account provides a range of analytics and insights relating to the Professionals activity v the rest of the relevant team/organisation or the wider ORCHA community. This data can be used to track activation levels within teams and practices and also to monitor adherence to agreed prescribing or recommendation protocols etc.

On an aggregated basis, this data can be used by organisations and systems to monitor overall activation and compliance rates and also to view the types of solutions that are being engaged with and those that are not.

The ORCHA Transformation Model envisages an iterative approach and this data can be used to refine and update formularies based on the real experiences of teams on the ground.

5.3 Pro Solutions Implementation Support

The deployment of ORCHA Pro Accounts comes with a base level of ORCHA Pro set-up and activation Support solutions which are delivered through a mixture of on the ground and remote approaches. These include:

- Pro Account set-up and configuration.

- Initial Pro training and familiarisation;
- Condition specific digital health training.

The level of support provided is developed on a case by case basis dependant on the specific deployment in question.

Where the ORCHA Transformation Model has been adopted, this will in effect replace the standard Implementation Support as that model, provides a highly structured and detailed implementation support component.

5.4 Pro-Solutions User Support

ORCHA operate 4 levels of user support. This includes:

- Online support tools, FAQ's and 'how to' resources
- e-ticket support
- telephony/web chat support
- Key account management

For our Review and Accreditation support we offer the following:

User Type	Support
All	Online support tools
All	e-ticketing
Client Administrators and ORCHA Pro-Account holders	telephony/web chat
Client Administrators/Key Account Contacts	direct account management

The relevant response and resolution KPI's for each support element can be found in Section 7. The key account management in the Review and Accreditation service includes ongoing access to the designated ORCHA Review Team lead throughout the duration of any agreement for the time specified in the relevant Client Agreement.

6 Additional Services

6.1 Data Insight Services

6.1.1 Background

ORCHA provide a unique Data and Insights service for a wide variety of clients who have a range of business requirements that require data, analytics and reporting.

ORCHA Data and Insights are underpinned by a comprehensive set of proprietary data and analytics that captures the nuanced nature of Digital Health, and through expert analysis services can be delivered through a range of technologies.

6.1.2 Data and Insights Service Components

6.1.2.1 Data

ORCHA harvest a range of datasets which are cleansed and combined to provide a rich dataset for mobile and web applications. These data include:

- Data available from the Google Play and Apple App stores is acquired from a 3rd-party for all Apps that fall into the Health & Fitness and Medical Categories. This includes App Description Data, all associated Meta-Data and User Reviews.
- Responses to over 250 questions from the ORCHA Baseline Review (OBR) is available for over 5,000 Apps.
- Assessment relating to the Enhanced Review Components (ERC) where these have been completed.
- Digital Application utilisation data that reflects User Engagement & Navigation, Usage Patterns, User Demographics.

6.1.2.2 Analytics

ORCHA apply several analytics to the combined dataset to ensure we are able to present information in a meaningful way for the client. These analytics include:

- Proprietary classification (categories and sub-categories) and scoring algorithms that underpin the ORCHA Baseline Review and ERC.
- Functional Capabilities and Behavioural Change Techniques.
- Topic-Sentiment analysis from App Store User Reviews.
- Proprietary utilisation measures and metrics.
- Identification of the drivers of healthcare service utilisation using patient-centred approach to identifying patients who are likely to benefit from digital health.
- Population Health opportunity analysis and RoI models including financial incentive and tariff design.

6.1.2.3 Technology / Deliverables

ORCHA Data and Insights can be provided via a range of technical solutions through our cloud services and infrastructure. Options include:

- Reports and analysis in document or presentation format.
- Raw data extracts with accompanying meta-data and data-dictionary/models.
- Canned and configurable reports that can be refreshed on a regular basis.
- Access through APIs to surface in client business intelligence and reporting solutions
- Secure web-based access to data, analytics and reporting tools that also support bespoke reporting.

Typically, deliverables include the following components with supporting narrative and analysis:

- Market opportunity and competitor analysis.
- Digital Health Trends and Bench-marking.
- In-depth Digital product and assessment reports.

6.2 User Focus Groups

User focus groups can form part of the initial Implementation Support but these additional days enable more focus or work with specific cohorts or geographies to refine the solution and implementation strategy.

6.3 Digital Attitudes Surveys

The Digital Attitudes Survey is a standard end user and professional user survey to establish the baseline attitudes and activity of the target population in terms of Digital Health. The baseline survey is then repeated at the end of the initial term to track the impact of the programme and to identify further areas for improvement in subsequent phases. The survey is a standard form to enable the results from other populations to be aggregated so that it is possible to gain an insight into the overall 'Digital Maturity' of a specific area or cohort. Any additional question sets can be incorporated as a bespoke adjustment, subject to agreeing the resource and cost impacts.

6.4 Enhanced Programme Impact Evaluation

The programme is supported with overall performance management information that tracks key platform usage and critical events and goals such as recommendations and downloads. This is done as part of the Implementation Support services. The enhanced evaluation links this data set with the Digital Attitudes data and other available insights, to create a richer and more nuanced evaluation of both the programme impact but also the Digital Maturity of the target audience. This supports both evaluation of the impact of the programme but also identifies key follow on actions and recommendations for subsequent initiatives. The enhanced evaluation can also work in concert with other initiatives and help support a wider integrated analysis of a range of digital health projects.

6.5 Video Case Studies

Another part of the overall programme evaluation, the Video case study can also be used as a resource to support implementation and activation strategies and to drive greater awareness and uptake of the solutions.

7 KPI's

7.1 Platform Availability

We will endeavour to ensure that the ORCHA Review Engine and Portals and relevant ORCHA APIs will be provided with a 99.7% availability rate (aside from scheduled

maintenance slots which will be restricted to off peak times between the hours of 18:00 and 8:00 UK time).

7.2 ORCHA User Support

We provide an online support management solution for end users and an online/telephone support solution for ORCHA Pro-Account users, Client Assessors and Client Administrators. The support function operates between the hours of 8:00 and 18:00 **UK** time on **Business Days**. The support function will look after all user and system related queries and bugs.

We will provide an online support function for all users which will operate a standard prioritisation process for 'tickets' raised. We will respond to:

- Priority 1 tickets within six (6) hours of receipt of Your notification to Us;
- Priority 2 tickets within twelve (12) hours of receipt of Your notification to Us; and
- Priority 3 tickets within twenty four (24) hours of receipt of Your notification to Us.

We will endeavour to resolve:

- Priority 1 tickets within forty-eight (48) hours (on a Business Day) and seventy-two (72) hours over the weekend;
- Priority 2 tickets within five (5) Business Days; and
- Priority 3 tickets within three (3) weeks,

following Our initial response.

Priority Definitions:

Priority 1	Critical	Interruption to the service making the system inaccessible or a complete network interruption causing a severe impact on the services availability. There is no workaround.
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Priority 2	Important	Non-critical function or procedure, unusable or hard to use having an operational impact, but with no direct impact on the services availability. A workaround is available.
Priority 3	Low	No impact on service availability or system usability – maybe a feature request or suggestion for improvement.

The relevant platform elements of the ORCHA Platform will be available during the term of the Contract. It will be decommissioned within four (4) weeks of the end of the Contract unless a further Contract has been put in place.

We will save all platform data for a period of three (3) months from the end of the Contract. This can be provided to You in csv. format upon request.

7.3 Review Delivery

We will use Our reasonable endeavours to:

- complete the assessment of any client requested OBR's within fourteen (10) days;
- to complete the assessment of any agreed ERC's within 24 days, of when an applicable relevant developer provides all necessary information and evidence; and
- deliver the Re-Review Protocol in accordance with the timescales set out in the relevant Review Specification.

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