



RCPCH Digital Growth Charts

Clinical Safety and Medical Device Documentation

Generated 26 June 2026

Clinical Safety of the dGC Project

Clinical Safety of these clinical tools is of paramount importance to us at the RCPCH. We are a standard-setting organisation with an international reputation and as such clinical safety has been at the forefront of our minds throughout the development of the project.

England, Wales and Scotland compliance

Our primary focus has been on clinical safety certification and Medical Device regulatory compliance **for the UK market and specifically England**, because the initial work on the dGC platform was commissioned by NHSX, which (at the time of commissioning) was an England-only body. We do however recognise the need for the dGC Platform to be recognised as safe for use in other UK nations including Northern Ireland and this is our next most important priority for regulatory compliance.

Other territories

Compliance for EU, US and other territories may follow, but will be subject to customer engagement in those countries or global regions. If you are an API consumer and you need the dGC platform to be certified in your region of operation, then please [get in touch with us](#) and we can discuss the requirements. Note that **different growth chart references** (eg WHO, CDC) are used in other countries, and we may need to commission further development of the API functions in order to support these. Adding new references is not technically difficult, but mandates significant testing and assurance processes.

Clinical Safety

Open Source, Transparency and Open Governance

In addition to the standard NHS clinical safety practices, a key aspect of the augmented clinical safety measures we have taken with the dGC platform is the open source codebase and completely open governance profile of the project.

Our entire codebase is open for inspection by other specialists, in a manner similar to the open peer review of academic publications, which ensures high quality by enabling others to replicate our results and verify or challenge the veracity of the calculations and testing independently. (Note the Digital Growth Charts do not **rely** on external validation - they are extensively internally tested)

DCB0129 and DCB0160 Compliance

We comply with the requirements of DCB0129 and DCB0160, and for details you can go [here](#) to review our entire Clinical Safety Management File.

Hazard Logs

Our Hazard Logs are managed on GitHub in the open. Details of how this works are [here](#).

Project Board

The members of the Project Board, a clinical expert group who oversee and advise on the clinical aspects of the development and ongoing maintenance and operation of the dGC Platform, are listed [here](#)

The Project Board decided on all changes to the **nature** of Growth Charts which came into effect during the dGC project - such as the application of Gestational Age Correction *throughout* the chart (instead of stopping at either 1 or 2 years of age, depending on the degree of prematurity, as was previously the case), and the abolition of the use of the averaged Term reference between 37 and 42 weeks.

Digital Technology Assessment Criteria (DTAC)

- DTAC is a UK(England)-only grouping of assessment criteria. It is relatively new, and aims to simply bring together and harmonise *existing* assessment criteria for digital technologies. More information is available on [the NHSX website](#)
- DTAC incorporates the DCB0129 and DCB0160 standards for clinical safety, which the RCPCH dGC platform is compliant with.

More information on our DTAC compliance is [here](#)

Clinical Safety Overview

Clinical Risk Management System

Royal College Digital Growth Charts Team

March 2021

Document Management

Revision History

- This document is versioned in Git and published in GitHub.
- Refer to the document's Releases section in GitHub to see a history of releases.
- This document was created from the [CRMP](#) template provided on the [NHS Digital Website](#).

Reviewers and Process

This document must be reviewed by:

- Dr Simon Chapman
- Prof Tim Cole
- Magda Umerska

The review mechanism for update is via Pull Request review on GitHub, with opportunity for reviewers to comment and amend the text.

Approvers and Process

This document must be **approved** by:

- Dr Marcus Baw - Clinical Safety Officer, [RCPCH dGC Team](#)
- Following satisfactory review by the Reviewers, the nominated Approvers merge the pull request into the main branch of the code.
- The current version of this document will always be selected as the 'default branch' in GitHub####
Related Documents

Introduction

This Clinical Risk Management System ([CRMS](#)) outlines the processes to be followed to ensure that all healthcare IT used to support care within the Organisation is developed, implemented and used in a safe manner.

This [CRMS](#) provides a framework that promotes the effective risk management, by the Organisation, of potential health IT hazards and operational incidents.

This [CRMS](#) complements existing risk management processes that should be defined in the Royal College Digital Growth Charts Team's Risk Management Strategy and wherever practical, uses existing procedures, processes and governance arrangements.

This CRMS addresses the requirements of [DCB0129](#) and [DCB0160](#) and follows best practice in clinical safety, development practice, security, and transparency.

This CRMS will be reviewed and maintained in accordance with the the Royal College Digital Growth Charts Team's policies.

Clinical Safety

Clinical Risk Management Plan

Document Controls

As part of our commitment to automation, transparency and open governance, this document's versioning is managed using the **Git** Distributed Version Control Software (**DVCS**), and the **GitHub** online code repository platform. These are currently regarded as the 'industry standard' for **DVCS** and online repositories, and are used by the majority of open and closed source developers worldwide. We also maintain our application and library code in Git and GitHub, meaning that our clinical safety case and documentation is managed close to our actual code.

Using the combination of Git and GitHub removes much of the manual work of maintaining document control processes, and so we have abandoned manual document controls entirely, in favour of GitHub's automatically updated controls.

To see the contributors to the documentation site you can view them here on GitHub. Contributors: <https://github.com/rcpch/digital-growth-charts-documentation/graphs/contributors>

Most recent update:

Purpose

The aim of the Clinical Risk Management Plan is to ensure that all of the **RCPCH** Digital Growth Charts Team involved with the development, implementation and use of healthcare IT systems are aware of the activities that are required to be undertaken to ensure patient safety is improved rather than compromised from the introduction of healthcare IT systems.

The **RCPCH** Digital Growth Charts Team is required to adhere to National Information standards created and monitored via the Data Coordination Board (**DCB**) within **NHS** Information Standards frameworks.

The mechanisms used are approved Clinical Risk Management System compliance documents.

This Clinical Risk Management System will be reviewed periodically to ensure that:

- changes in working practices are incorporated.
- issues identified through an established internal audit programme are addressed.
- the safety approach continues to adhere to the requirements of applicable international standards.
- the system continues to protect the safety of patients in a complex and changing environment.

Audience

This document is for the **RCPCH** Digital Growth Charts Team staff that are involved in ensuring the safety of the **RCPCH**'s healthcare IT systems, products or services, but is made publicly available as part of our commitment to transparency and open governance.

Scope

This policy applies to the the RCPCH Digital Growth Charts Team's organisation and to all of the RCPCH Digital Growth Charts Team's IT systems. The policy also applies to any local customisations, upgrades or specific configurations made to a healthcare IT system by the RCPCH Digital Growth Charts Team.

If clarification is required of whether any system falls within scope of this CRMS this should be raised with the nominated Clinical Safety Officer (CSO) for clarification. This nominated person provides clinical and organisational leadership on healthcare IT Patient Safety on behalf of the Organisation.

IMPORTANT NOTICE FOR SELF-HOSTING

IMPORTANT: This Clinical Risk Management File applies **ONLY** to RCPCH open source software as deployed and managed by the RCPCH Digital Growth Charts Team under our direct control.

Self Hosting - Clinical Safety Risk

TL;DR: Don't self-host in production. Use our warranted API.

The only version of the Digital Growth Charts API which is warranted to be correct for clinical use is that which is served by the RCPCH itself from our API endpoint at <https://api.rcpch.ac.uk>.

For reasons of transparency, equity-of-access and safety, we have made it *possible* to use our open-source code to set up a server providing Digital Growth Charts API calculations. **However, we strongly advise against doing this**, except for testing, verification, development purposes or research (which is not for academic publication).

WE STRONGLY RECOMMEND NOT TO SELF-HOST THE SERVER FOR PRODUCTION, CLINICAL or other 'LIVE' USE.

By self-hosting, you would not have a warranty from the RCPCH: you are liable for misconfigurations in the server leading to clinical issues. To ensure safe service with the complexity of Growth Charts, you likely require large amounts of statistical, clinical and technical consultancy.

You must understand and accept that any version of this API running **outside** our controlled environment must have been:

1. Independently **technically-assured**, such that the platform, deployment, and modifications are secure, safe, and reliable.
2. Independently **clinically-assured**, such that the application is safe and has a qualified Clinical Safety Officer, a Clinical Safety Management File, and is fully compliant with DCB0129 and DCB0160.
3. Registered with the MHRA as a Medical Device (for UK deployment) and EU MDR, with Declaration of Conformity (for EU deployment).

For this reason, we STRONGLY recommend you DO NOT SELF-HOST any of our platform, but instead use the hosted (and attractively-priced) Digital Growth Charts API platform. Self-hosting means your organisation is fully liable for any errors in calculation, deployment, or functioning. We will not provide any free support for self-hosting organisations.

Definitions

Note - Also see the RCPCH Risk Management Strategy

CSO: Clinical Safety Officer - the person responsible for ensuring that the healthcare IT Clinical Risk Management System is applied to all clinical systems. The Clinical Safety Officer (CSO) for the Organisation is responsible for ensuring the safety of a healthcare IT system through the application of clinical risk management. The Clinical Safety Officer must hold a current registration with an appropriate professional body relevant to their training and experience. They also need to be suitably trained and qualified in risk management or have an understanding in principles of risk and safety as applied to healthcare IT systems. The Clinical Safety Officer ensures that the processes defined by the clinical risk management system are followed.

DCB: Data Coordination Board

Healthcare IT Clinical Risk Management (CRM) Governance Arrangements

The responsibility for healthcare IT CRM within the Organisation resides with the Clinical Safety Officer

Organisational management of healthcare IT related risks is as per the existing management arrangements as specified in the Organisation's Risk Management Strategy.

Clinical Risk Management Team Organisation Chart

The RCPCH's team is not yet of a size that it requires an org chart to explain. Left here as a placeholder in case an org chart is needed in the future.

Personnel

Clinical Safety Officer

Dr Marcus Baw NHS Digital-trained Clinical Safety Officer
Registered General Medical Practitioner, GMC Number 4712729
Software Developer
Github [@pacharanero](#)

Senior Clinical Adviser

Dr Simon Chapman Consultant Paediatrician, King's College Hospital Trust
Specialist in Diabetes and Endocrinology
Software Developer
Github [@eatyourpeas](#)

Chief Digital Officer

Richard Burley Chief Digital Officer, RCPCH

Chief Executive Officer

Overall governance for the RCPCH Digital Growth Charts project is provided not by a single individual, but by the [RCPCH Digital Growth Charts Project Board](#), which is composed of senior leadership within the RCPCH and the most eminent clinicians in the field of Growth charts.

Governance

Governance for patient safety within the Organisation is provided through the following forums:

Clinical Risk Meetings

- Clinical Safety is discussed as a fixed item on the two-weekly Sprint Planning Meeting at which the project is planned and priorities set for the next sprint of development.
- In the event of an **urgent** clinical safety issue or incident, a supplementary Clinical Risk meeting is held at the earliest possible time.

Open, transparent public Issue tracking

- Open, public issue tracking ensures the widest possible reporting base, and unparalleled access to report issues compared to the majority of Health IT systems. These Issues, tracked in GitHub, directly form part of the development workflow used by the clinical and technical teams.

Public forum

RCPCH maintains a web forum (forum.rcpch.tech), where users, implementers, and clinicians can feed back on the system. This is a transparent and open mechanism for safety feedback and aftermarket surveillance of the platform. Using the same system or using our contact page it is also possible to send a private message or contact via email in the event of a private communication being necessary.

Healthcare IT Clinical Risk Management Deliverables

Clinical Risk Management File CRMF (this repository)

The RCPCH Digital Growth Charts Team will establish a Clinical Risk Management File (CRMF) for each safety related healthcare IT system. The purpose of the CRMF is to provide a central repository where all safety related information pertaining to the healthcare IT system is stored and controlled. This GitHub repository contains our Clinical Risk Management File.

Clinical Risk Management Plan CRMP (this document)

The RCPCH Digital Growth Charts Team will establish a Clinical Risk Management Plan (CRMP) for each safety related healthcare IT system. The purpose of the CRMP is to identify the clinical risk management activities that are to be undertaken and the phasing of these activities in the project lifecycle.

The CRMP will also identify the resources required to discharge these clinical risk management activities.

Hazard Log

The RCPCH Digital Growth Charts Team will establish and maintain a Hazard Log (HL) for each safety related healthcare IT system. The HL will be controlled and configured in accordance with the RCPCH Digital Growth Charts Team's document control policy.

The Hazard Log details can be viewed on the [Hazard Log page](#)

Clinical Safety Case

The RCPCH Digital Growth Charts Team will establish and develop a Clinical Safety Case (CSC) for each safety related HIT system:

- [RCPCH dGC Application Programming Interface](#)

Clinical Safety Case Report

The RCPCH Digital Growth Charts Team will issue a Clinical Safety Case Report (CSCR) for each safety related healthcare IT system. The CSCR will be issued to support initial deployment and will be updated during the lifecycle of the Healthcare IT system should the safety characteristics change. The CSCR will be controlled and configured in accordance with the RCPCH Digital Growth Charts Team's document control policy. The Hazard Log will be made available within the CRME.

- [RCPCH dGC Application Programming Interface](#)

Healthcare IT Clinical Risk Management Activities

Hazard Identification

The RCPCH Digital Growth Charts Team will conduct hazard identification workshops to identify potential hazards associated with the deployment and use of our healthcare IT system. The CSO will be responsible for facilitating such workshops and ensuring attendance from the RCPCH Digital Growth Charts Team.

Typically, representatives from the following domains will be required:

- Technical testing team
- User research and User Experience team
- Clinical testing team
- Statistical support
- Project Board

If a healthcare IT solution is deemed not to be safety related then this decision will be formally recorded.

The technical team will advise on the best mechanism for addition of new issues to the the RCPCH Digital Growth Charts Team's project management workflow.

Where any third-party components are used to support the healthcare IT system then they will be considered in the scope of the hazard identification activities and subsequent risk assessment. Where none are used a positive declaration to this effect will be recorded in the minutes.

All identified hazards will be recorded in the [Hazard Log](#).

Risk Assessment

The RCPCH Digital Growth Charts Team will conduct healthcare IT system risk assessment in accordance with the Risk Management Strategy. The Hazard Log will be updated to capture the risk assessment.

Risk Evaluation

The RCPCH Digital Growth Charts Team will conduct healthcare IT system risk evaluation in accordance with the Risk Management Strategy The Hazard Log will be updated to capture the risk evaluation.

Risk Control

Where the initial risk evaluation is deemed unacceptable, further risk controls will be required. The RCPCH Digital Growth Charts Team will manage healthcare IT system risk in accordance with the Risk Management Strategy.

Details of the risk control measures and evidence of effective implementation will be captured in the Hazard Log.

Deployment and Ongoing Maintenance

To support clinical safety activities undertaken during any deployment phases of a project or programme of work the following documentation will be required to form a part of the overall approval process.

Deployment of changes to any of the RCPCH dGC Health IT systems follows an industry-standard pattern of 'code promotion' using a Git Branch-based strategy. New features are developed in branches specific to that feature. Following successful testing, user acceptance, and automated tests, a successful feature can be merged into the next branch 'up' which may be a `test` branch or other nomenclature. The process of merging requires code review by nominated individuals and is a further opportunity for clinical safety review.

Code in the `live` branch is changed relatively infrequently (except for urgent security or safety updates) but the code which is promoted into `live` would have by then undergone several rounds of review as it progressed through our branch promotion strategy.

Incident Management

Clinical Risk Management activities within the Organisation and the healthcare IT programmes and services offered are completed within the corporate risk management strategy. As such, clinical safety related incidents are dealt with in a similar manner as other incidents within the organisation such as financial, reputational, technical and other service-impacting categories.

Safety Incident Management Process

The first step in any possible Safety Incident is to inform the Clinical Safety Officer. The CSO will determine the most appropriate course of action and will record the incident, the hazards identified (if any) and the mitigations and other remediation taken in a GitHub Issue relevant to the software element in question. Senior management of RCPCH will be informed at the earliest opportunity.

Security Incident Management Process

Security issues may be responsibly disclosed to growth.digital@rcpch.ac.uk for immediate action. We recognise and respect the work of security researchers and will treat your contribution with gratitude and appropriate action. We do not engage in vexatious CMA litigation.

Internally we treat security issues with the highest priority. Once the 'acute phase' of any security threat is handled, we will then follow the Safety Incident Management Process, usually converting to a public GitHub Issue.

Clinical Safety Competence and Training

Overview

The clinical safety activities described in this Clinical Risk Management System shall be undertaken by competent staff. Suitable training shall be undertaken by staff to maintain and expand their level of competence.

Competency

All of the staff identified in the clinical safety documentation shall be sufficiently competent for the roles and tasks which they are asked to undertake. Where an individual does not yet have sufficient experience or knowledge, then that person shall be monitored, and his/her work reviewed, by someone who has the necessary competence. Such supervision shall prevail until it is judged that the individual has amassed the necessary experience to undertake such tasks unsupervised.

In assessing competency, the different functional roles required to fully discharge the obligations of the Clinical Risk Management System, and the necessary skills and knowledge needed for each, shall be considered. Primary functional roles may include: - Conducting discrete safety analyses (for example, a HAZOP or FFA) or defining the Hazard Risk Indicators for a particular project.

- Making a valid judgement on the safety tasks, activities and techniques required for a given Health Software Product in order to justify the comprehensiveness and completeness of the safety assessment and produce the safety argument with supporting evidence.
- Assurance of safety assessments and healthcare IT software products. Performance of safety techniques and development of the safety argument for a particular healthcare IT software product must be independent to any assurance activities for the same.
- Improving and refining the overall Clinical Risk Management System, for example, audit, process change, quality.
- Ownership and leadership, for example, ultimate safety accountability, culture change, influencing and strategic direction.
- The first test in establishing competency shall be at the interview stage where potential staff shall be assessed against the above representative roles and agreed job descriptions. Thereafter, competence shall be monitored through the organisation's established appraisal scheme. Any perceived deficiencies identified during the course of the work or at the appraised stage, especially during probation, shall be addressed immediately, for example, through the assignment of a competent supervisor or the provision of suitable training.
- All registered clinicians involved in safety roles shall, as a minimum, have completed an accredited training course.

Training

- As part of the employment process and thereafter through the appraisal scheme, clinical safety personnel will undergo suitable training to develop, maintain or enhance their competency level. Such training can comprise: - 'on the job' training conducted under supervision - Internal training courses - Approved external training courses.

- All registered clinicians involved in clinical safety roles shall, as a minimum, have completed an accredited training course.
- Completion of any safety training shall be recorded by the individual on the annual appraisal form.

Audits

Overview

Audits shall be undertaken to ensure that projects are adhering to the defined safety requirements. Such audits will focus on the **Clinical Safety Team** and **third-party** suppliers.

Internal Safety Audits

- the RCPCH Digital Growth Charts Team shall undertake regular internal safety audits to ensure that projects undertaken within the organisation are compliant with this Clinical Risk Management System. These audits shall be conducted and recorded in accordance with the internal quality management procedure.
- The scope of an internal safety audit will be the formal Clinical Risk Management System and the organisation's documentation supporting this document.

Supplier Audits

The RCPCH Digital Growth Charts Team shall undertake regular third-party supplier audits, as a minimum annually, to ensure compliance with their Clinical Risk Management System. The audit shall focus on the Clinical Risk Management System, the evidence which demonstrates its effective operation and any issues arising from the deployment of the healthcare IT products and services. The basis for the audit shall be DCB0129.

Clinical Safety

Clinical Safety Case Report for the RCPCH Digital Growth Charts Platform

Document Controls

Version control	
The latest revision of this document is recorded in the commit history here: https://github.com/rcpch/digital-growth-charts-documentation/commits/live/docs/safety/csmf .	
Reviewers	
Dr Marcus Baw	Lead Developer, General Practitioner, Clinical Safety Officer
Dr Simon Chapman	Lead Developer, Consultant Paediatrician, Clinical Safety Officer
Approvers	
Dr Marcus Baw	Clinical Safety Officer

Introduction

The purpose of the DCB0129 Clinical Safety Case Report is to describe the clinical safety processes and assurances applied to the RCPCH Digital Growth Charts Platform in its manufacture. In deployment or implementation, a further DCB0160 clinical safety case will be required.

System Definition / Overview

The RCPCH Digital Growth Charts Platform consists of a suite of software tools which together enable the calculation and display of important growth-related parameters for children ranging in age from severely premature up to the age of around 20.

For the purposes of this Safety Case, the principal components are:

1. [The Digital Growth Charts API](#), which receives growth measurements and returns growth calculations.
2. [The React Chart Component](#), which takes the returned growth calculation JSON data and displays as a HTML-based RCPCH standard visual growth chart that is familiar to clinicians.
3. [The RCPCH Growth Python Library](#), which provides the calculation functionality within the API Server.

Intended Use

The RCPCH Digital Growth Charts Platform is intended to be deployed within other systems, principally Electronic Patient Records (EPRs), Electronic Health Records (EHRs), Personal Health Records (PHRs), and other software platforms. **ONLY The commercial subscription API service provided by the RCPCH is warranted to have undergone the testing and assurance described in this document.**

DISCLAIMER

If using the API service in any other 'unofficial' way, such as self-hosting, reverse-engineering, or misusing internal dGC components outwith the RCPCH Platform - this is deemed to be usage outwith any provisions of this document. The RCPCH Clinical Safety Officer expressly disclaims any responsibility for usage of the RCPCH dGC Platform outwith of its intended commercial use.

The intended user of these digital growth charts is a healthcare professional with sufficient training and knowledge to be able to understand the meaning of the values or charts displayed. Although growth charts have been present in the Red Book for parents to see for many years, parents are unlikely to have the understanding of the charts to operate or interpret the charts independently. Parents may freely be given access to charts but the interpretation of a growth trend remains a clinician task.

Growth charts are only **one** of numerous sources of information available to a clinician when assessing a patient. They do not in themselves provide a diagnosis and can only be helpful as **part** of a full assessment of the patient. Clinicians must actively seek other confirmatory evidence for conclusions reached by their use of a growth chart.

Although the utmost care has been taken during the design and delivery of the dGC platform, the RCPCH and its Digital Growth Charts team accept no responsibility for clinical errors made where the chart has been misinterpreted or an operator of insufficient training has used them wrongly.

Clinical Risk Management System

A full description of the Clinical Risk Management System in place at the RCPCH is detailed in the section on [Clinical Risk Management System](#).

Clinical safety and risk management are well-embedded within the culture of the RCPCH and its Digital Incubator Team.

The Clinical Risk Management File is currently maintained by the [Clinical Safety Officer](#), and contains all the relevant documentation related to the clinical safety of the RCPCH Digital Growth Charts Platform.

The Clinical Safety Officer (CSO) is responsible for clinical safety of RCPCH Digital Growth Charts Platform, through the application of clinical risk management procedure. The CSO is a suitably qualified and experienced clinician who holds current registration with their relevant professional body and has had appropriate training for this role. In the RCPCH the CSO role is held by one of the lead developers.

Clinical Risk Analysis

Hazard Identification Workshops were held, involving the entire RCPCH dGC Project Board, the Clinical Safety Officer, the Development team, and the supporting RCPCH staff team, at which hazards affecting the Digital Growth Charts were discussed and the risk levels identified.

Hazard Log

A [Hazard Log](#) was established using GitHub Issues as a mechanism for logging the Hazard, quantifying risk severity and likelihood and overall risk level. Steps were then taken to reduce and mitigate risks down to acceptable levels, using the [DCB0129](#) definitions for acceptability.

More detail of the individual risks and descriptions of the pre- and post-mitigation risk levels are within the text of each of the Hazards in the Hazard Logs.

Likelihood	Very High	3	4	4	5	5
	High	2	3	3	4	5
	Medium	2	2	3	3	4
	Low	1	2	2	3	4
	Very Low	1	1	2	2	3
		Minor	Significant	Considerable	Major	Catastrophic
Severity						

Hazard: Unavailability of the dGC API calculation and charting functions

<https://github.com/rcpch/digital-growth-charts-documentation/issues/51>

Description of initial Risk and mitigation steps

The API server runs on high-availability Microsoft Azure public cloud infrastructure and is hardened to above industry standard.

The Project Board felt the unavailability of the API would be unlikely to cause any form of harm to a patient because there are immediately available fallback methods such as manual calculation on printed paper charts.

Severity

Minor

Likelihood

Medium

Residual Risk Level

Outcome

| | Level 1 - Acceptable |

| | RCPCH endeavours to ensure that implementer organisations have appropriate support in order to reduce the risk of errors in passing data to the API | Level 1 - Transferred | | Misuse of the API code by external organisations

Hazard: Wrong data is *entered into* the Digital Growth Chart API

Description of initial Risk and mitigation steps

In both the above scenarios, our Project Board of clinical paediatrics and growth experts agreed that the absolute risk of directly attributable harm to a child is rather low, because of the multiple clinical practice safeguards that exist whether the growth chart is paper, PDF or digital.

Severity

Likelihood

Residual Risk Level

Outcome

RCPCH endeavours to ensure that implementer organisations have appropriate support in order to reduce the risk of errors in passing data to the API, however much of the implementation risk must necessarily be passed on to the DCB0160 clinical safety assessment.

Hazard: Incorrect centile data is *returned by* the API

Description of initial Risk and mitigation steps

Prior to deployment of the Digital Growth Charts, significant 'static' software testing was performed, to ensure that the complex statistical calculations returned by the API had been confirmed to have a very high degree of conformity to previous statistical Centile calculation engines, across a synthetic 'test harness' of approximately 4000 children's data. It is worth noting that the agreement between the systems was to 4 decimal places, the small variation between these is accounted for by the fact that statistics uses complex modelling of curves and interpolation, so it is impossible to get perfect alignment between two systems written in different languages (in this case, R and Python).

This testing process was supervised directly by Prof Tim Cole, a distinguished UK Child Health statistician and the originator of using the LMS Method for centile charts. The degree of error in calculation was deemed to be clinically insignificant, representing around *one-ten-thousandth* of a Centile percentage point, in a clinical measurement context in which significant variations are found simply in the measurement technique itself (for example weighing and measuring a moving baby).

End-to-end testing of the platform was also manually performed to 'spot check' that the data entered for a generated synthetic child was corroborated against analogue calculations of centile values.

Severity

Major

Likelihood

Very Low

Residual Risk Level

Outcome

Hazard: Misuse of the API code by external organisations

Description of initial Risk and mitigation steps

Severity

Likelihood

Residual Risk Level

Outcome

Test Issues

There are no outstanding test issues from a [DCB0129](#) standpoint. Implementers will be expected to conduct their own User Acceptance Testing as part of development and roll-out of their solution, and their feedback may inform future development of the [RCPCH](#) Digital Growth Charts Platform.

Summary Safety Statement

This document recommends that the [RCPCH](#) Digital Growth Charts platform is suitable for clinical deployment and use, subject to further [DCB0160](#) clinical risk management within the deploying organisation, and with support from the [RCPCH](#) in correct and safe deployment.

Quality Assurance and Document Approval

This document is currently written by the [CSO](#) with support from the [RCPCH](#) Incubator and Development Team who have undergone the necessary training on clinical safety in Healthcare IT systems. The other activities which support the creation of this document include the hazard identification workshops which are supported by the [RCPCH](#) Project Board and other clinical and administrative staff.

This report is then reviewed by the Deputy Clinical Safety Officer, Lead Developers, [dGC](#) Product Owner, [dGC](#) Project Manager, and Chief Digital Officer before a recommendation is made.

Clinical Safety

Digital Growth Charts Hazard Log

In keeping with our commitment to transparency and openness, our Hazard Log is **publicly** visible and managed in GitHub using the Issues feature.

Each Issue represents a Hazard potentially affecting the project.

Hazards can be viewed (and indeed commented on, discussed, and improved) at the URL below:

<https://github.com/rcpch/digital-growth-charts-documentation/issues>

Instead of the more usual and somewhat outdated and chaotic 'spreadsheet' model, often used for Hazard Logs, we are using the [Issues](#) facility in GitHub to record Hazards.

- *Labels* are used to annotate Hazard Issues with `severity-` and `likelihood-` scores, from which we can derive a `risk-level-`. See all Labels [here](#)
- *Milestones* are used to designate the Initial Risk Assessment and Residual Risk Assessment. See all Milestones [here](#)

Most importantly, the **discussion and evidence** relating to any given risk is included in the recording of the risk. A complete history of the labelling is kept in the issue. Spreadsheet-based risk and hazard handling is inferior to this model, because spreadsheets are unsuited to discussion, text handling, and long-form discourse.

Beware of spreadsheets

A Hazard which is *never* recorded in any Spreadsheet-based Hazard Log is 'Accidental deletion of a Hazard before it has been mitigated/risk-eliminated', yet anyone who has used a spreadsheet knows how easy it is to accidentally delete or modify a cell or row inadvertently. Put simply, a spreadsheet is a poor choice of technology for managing text and a totally unacceptable choice of technology for handling Hazards, yet it has become the industry standard across the [NHS](#) simply because the Hazard Log template issued by [NHS Digital](#) is a spreadsheet.

Monitoring of Risk

Using the Label search feature, one can search for Hazards at any Risk Level, in order to triage the most risky Hazards for further action.

[risk-level-5-unacceptable](#)

[risk-level-4-mandatory-risk-elimination](#)

[risk-level-3-undesirable](#)

[risk-level-2-acceptable](#)

[risk-level-1-acceptable](#)

- We can filter for multiple labels.

Deletion

Hazards are **never** deleted but may be *closed* if no longer relevant.

Alternative views

We are planning to develop a simple application which can view Issues in a tabular form, for familiarity.

Creating a Hazard

1. Navigate to [Issues](#)
2. Click on New Issue
3. Use the **Hazard Issue Template** to guide you through adding the necessary information.
4. Label according to Severity and Likelihood, then calculate Risk Level.
5. Assign to [CSO](#) @pacharanero.
6. Save by 'committing' to the repository.
7. Review and ensure complete.
8. Invite others to review and comment using @mention or by sharing the URL

Hazard Table

Please refer to the [RCPCH dGC Hazard Log GitHub Project](#)

Clinical Safety Hazards

Third Party Tools Safety

This section documents the steps taken in order to minimise risk incurred from using third party tools in our software stack. Each of the tools is selected

List of Third Party Tools

Python FastAPI React.js

Cloud Services Providers

Microsoft Azure GitHub

Clinical Safety

License file for the RCPCH dGC Clinical Safety Management File

This clinical safety management file is unusual in that it is in a public repository. Having completely open clinical safety documentation is a good way to increase transparency and to demonstrate genuine attention to clinical safety issues.

We are happy for it to be reused by others implementing open source projects. If you do reuse any part of this work, you **must** attribute the Royal College of Paediatrics and Child Health, and follow the other terms of this license. If you are a commercial organisation wishing to use this documentation then we may consider dual-licensing to allow for this. Please contact us.



RCPCH dGC Clinical Safety Management File by [Royal College of Paediatrics and Child Health](#) is licensed under a [Creative Commons Attribution-ShareAlike 4.0 International License](#).

Creative Commons Attribution-NonCommercial-ShareAlike 4.0 International

Creative Commons Corporation (“Creative Commons”) is not a law firm and does not provide legal services or legal advice. Distribution of Creative Commons public licenses does not create a lawyer-client or other relationship. Creative Commons makes its licenses and related information available on an “as-is” basis. Creative Commons gives no warranties regarding its licenses, any material licensed under their terms and conditions, or any related information. Creative Commons disclaims all liability for damages resulting from their use to the fullest extent possible.

Using Creative Commons Public Licenses

Creative Commons public licenses provide a standard set of terms and conditions that creators and other rights holders may use to share original works of authorship and other material subject to copyright and certain other rights specified in the public license below. The following considerations are for informational purposes only, are not exhaustive, and do not form part of our licenses.

- **Considerations for licensors:** Our public licenses are intended for use by those authorized to give the public permission to use material in ways otherwise restricted by copyright and certain other rights. Our licenses are irrevocable. Licensors should read and understand the terms and conditions of the license they choose before applying it. Licensors should also secure all rights necessary before applying our licenses so that the public can reuse the material as expected. Licensors should clearly mark any material not subject to the license. This includes other CC-licensed material, or material used under an exception or limitation to copyright. [More considerations for licensors](#).
- **Considerations for the public:** By using one of our public licenses, a licensor grants the public permission to use the licensed material under specified terms and conditions. If the licensor’s permission is not necessary for any reason—for example, because of any applicable exception or limitation to copyright—then that use is not regulated by the license. Our licenses grant only permissions under copyright and certain other rights that a licensor has authority to grant. Use of the

licensed material may still be restricted for other reasons, including because others have copyright or other rights in the material. A licensor may make special requests, such as asking that all changes be marked or described. Although not required by our licenses, you are encouraged to respect those requests where reasonable. [More considerations for the public.](#)

Creative Commons Attribution-NonCommercial-ShareAlike 4.0 International Public License

By exercising the Licensed Rights (defined below), You accept and agree to be bound by the terms and conditions of this Creative Commons Attribution-NonCommercial-ShareAlike 4.0 International Public License ("Public License"). To the extent this Public License may be interpreted as a contract, You are granted the Licensed Rights in consideration of Your acceptance of these terms and conditions, and the Licensor grants You such rights in consideration of benefits the Licensor receives from making the Licensed Material available under these terms and conditions.

Section 1 – Definitions.

- a. **Adapted Material** means material subject to Copyright and Similar Rights that is derived from or based upon the Licensed Material and in which the Licensed Material is translated, altered, arranged, transformed, or otherwise modified in a manner requiring permission under the Copyright and Similar Rights held by the Licensor. For purposes of this Public License, where the Licensed Material is a musical work, performance, or sound recording, Adapted Material is always produced where the Licensed Material is synched in timed relation with a moving image.
- b. **Adapter's License** means the license You apply to Your Copyright and Similar Rights in Your contributions to Adapted Material in accordance with the terms and conditions of this Public License.
- c. **BY-NC-SA Compatible License** means a license listed at creativecommons.org/compatiblelicenses, approved by Creative Commons as essentially the equivalent of this Public License.
- d. **Copyright and Similar Rights** means copyright and/or similar rights closely related to copyright including, without limitation, performance, broadcast, sound recording, and Sui Generis Database Rights, without regard to how the rights are labeled or categorized. For purposes of this Public License, the rights specified in Section 2(b)(1)-(2) are not Copyright and Similar Rights.
- e. **Effective Technological Measures** means those measures that, in the absence of proper authority, may not be circumvented under laws fulfilling obligations under Article 11 of the WIPO Copyright Treaty adopted on December 20, 1996, and/or similar international agreements.
- f. **Exceptions and Limitations** means fair use, fair dealing, and/or any other exception or limitation to Copyright and Similar Rights that applies to Your use of the Licensed Material.
- g. **License Elements** means the license attributes listed in the name of a Creative Commons Public License. The License Elements of this Public License are Attribution, NonCommercial, and ShareAlike.
- h. **Licensed Material** means the artistic or literary work, database, or other material to which the Licensor applied this Public License.
- i. **Licensed Rights** means the rights granted to You subject to the terms and conditions of this Public License, which are limited to all Copyright and Similar Rights that apply to Your use of the Licensed Material and that the Licensor has authority to license.

j. **Licensor** means the individual(s) or entity(ies) granting rights under this Public License.

k. **NonCommercial** means not primarily intended for or directed towards commercial advantage or monetary compensation. For purposes of this Public License, the exchange of the Licensed Material for other material subject to Copyright and Similar Rights by digital file-sharing or similar means is NonCommercial provided there is no payment of monetary compensation in connection with the exchange.

l. **Share** means to provide material to the public by any means or process that requires permission under the Licensed Rights, such as reproduction, public display, public performance, distribution, dissemination, communication, or importation, and to make material available to the public including in ways that members of the public may access the material from a place and at a time individually chosen by them.

m. **Sui Generis Database Rights** means rights other than copyright resulting from Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases, as amended and/or succeeded, as well as other essentially equivalent rights anywhere in the world.

n. **You** means the individual or entity exercising the Licensed Rights under this Public License. **Your** has a corresponding meaning.

Section 2 – Scope.

a. *License grant.*

1. Subject to the terms and conditions of this Public License, the Licensor hereby grants You a worldwide, royalty-free, non-sublicensable, non-exclusive, irrevocable license to exercise the Licensed Rights in the Licensed Material to:

A. reproduce and Share the Licensed Material, in whole or in part, for NonCommercial purposes only; and

B. produce, reproduce, and Share Adapted Material for NonCommercial purposes only.

2. **Exceptions and Limitations.** For the avoidance of doubt, where Exceptions and Limitations apply to Your use, this Public License does not apply, and You do not need to comply with its terms and conditions.
3. **Term.** The term of this Public License is specified in Section 6(a).
4. **Media and formats; technical modifications allowed.** The Licensor authorizes You to exercise the Licensed Rights in all media and formats whether now known or hereafter created, and to make technical modifications necessary to do so. The Licensor waives and/or agrees not to assert any right or authority to forbid You from making technical modifications necessary to exercise the Licensed Rights, including technical modifications necessary to circumvent Effective Technological Measures. For purposes of this Public License, simply making modifications authorized by this Section 2(a)(4) never produces Adapted Material.
5. **Downstream recipients.**

A. **Offer from the Licensor – Licensed Material.** Every recipient of the Licensed Material automatically receives an offer from the Licensor to exercise the Licensed Rights under the terms and conditions of this Public License.

B. **Additional offer from the Licensor – Adapted Material.** Every recipient of Adapted Material from You automatically receives an offer from the Licensor to exercise the Licensed Rights in the Adapted Material under the conditions of the Adapter’s License You apply.

C. **No downstream restrictions.** You may not offer or impose any additional or different terms or conditions on, or apply any Effective Technological Measures to, the Licensed Material if doing so restricts exercise of the Licensed Rights by any recipient of the Licensed Material.

6. **No endorsement.** Nothing in this Public License constitutes or may be construed as permission to assert or imply that You are, or that Your use of the Licensed Material is, connected with, or sponsored, endorsed, or granted official status by, the Licensor or others designated to receive attribution as provided in Section 3(a)(1)(A)(i).

b. **Other rights.**

1. Moral rights, such as the right of integrity, are not licensed under this Public License, nor are publicity, privacy, and/or other similar personality rights; however, to the extent possible, the Licensor waives and/or agrees not to assert any such rights held by the Licensor to the limited extent necessary to allow You to exercise the Licensed Rights, but not otherwise.
2. Patent and trademark rights are not licensed under this Public License.
3. To the extent possible, the Licensor waives any right to collect royalties from You for the exercise of the Licensed Rights, whether directly or through a collecting society under any voluntary or waivable statutory or compulsory licensing scheme. In all other cases the Licensor expressly reserves any right to collect such royalties, including when the Licensed Material is used other than for NonCommercial purposes.

Section 3 – License Conditions.

Your exercise of the Licensed Rights is expressly made subject to the following conditions.

a. **Attribution.**

1. If You Share the Licensed Material (including in modified form), You must:
 - A. retain the following if it is supplied by the Licensor with the Licensed Material:

- i. identification of the creator(s) of the Licensed Material and any others designated to receive attribution, in any reasonable manner requested by the Licensor (including by pseudonym if designated);
- ii. a copyright notice;
- iii. a notice that refers to this Public License;
- iv. a notice that refers to the disclaimer of warranties;
- v. a URI or hyperlink to the Licensed Material to the extent reasonably practicable;

B. indicate if You modified the Licensed Material and retain an indication of any previous modifications; and

C. indicate the Licensed Material is licensed under this Public License, and include the text of, or the URI or hyperlink to, this Public License.

2. You may satisfy the conditions in Section 3(a)(1) in any reasonable manner based on the medium, means, and context in which You Share the Licensed Material. For example, it may be reasonable to satisfy the conditions by providing a URI or hyperlink to a resource that includes the required information.
3. If requested by the Licensor, You must remove any of the information required by Section 3(a)(1)(A) to the extent reasonably practicable.

b. *ShareAlike*.

In addition to the conditions in Section 3(a), if You Share Adapted Material You produce, the following conditions also apply.

1. The Adapter's License You apply must be a Creative Commons license with the same License Elements, this version or later, or a BY-NC-SA Compatible License.
2. You must include the text of, or the URI or hyperlink to, the Adapter's License You apply. You may satisfy this condition in any reasonable manner based on the medium, means, and context in which You Share Adapted Material.
3. You may not offer or impose any additional or different terms or conditions on, or apply any Effective Technological Measures to, Adapted Material that restrict exercise of the rights granted under the Adapter's License You apply.

Section 4 – Sui Generis Database Rights.

Where the Licensed Rights include Sui Generis Database Rights that apply to Your use of the Licensed Material:

- a. for the avoidance of doubt, Section 2(a)(1) grants You the right to extract, reuse, reproduce, and Share all or a substantial portion of the contents of the database for NonCommercial purposes only;

- b. if You include all or a substantial portion of the database contents in a database in which You have Sui Generis Database Rights, then the database in which You have Sui Generis Database Rights (but not its individual contents) is Adapted Material, including for purposes of Section 3(b); and
- c. You must comply with the conditions in Section 3(a) if You Share all or a substantial portion of the contents of the database.

For the avoidance of doubt, this Section 4 supplements and does not replace Your obligations under this Public License where the Licensed Rights include other Copyright and Similar Rights.

Section 5 – Disclaimer of Warranties and Limitation of Liability.

- a. **Unless otherwise separately undertaken by the Licensor, to the extent possible, the Licensor offers the Licensed Material as-is and as-available, and makes no representations or warranties of any kind concerning the Licensed Material, whether express, implied, statutory, or other. This includes, without limitation, warranties of title, merchantability, fitness for a particular purpose, non-infringement, absence of latent or other defects, accuracy, or the presence or absence of errors, whether or not known or discoverable. Where disclaimers of warranties are not allowed in full or in part, this disclaimer may not apply to You.**
- b. **To the extent possible, in no event will the Licensor be liable to You on any legal theory (including, without limitation, negligence) or otherwise for any direct, special, indirect, incidental, consequential, punitive, exemplary, or other losses, costs, expenses, or damages arising out of this Public License or use of the Licensed Material, even if the Licensor has been advised of the possibility of such losses, costs, expenses, or damages. Where a limitation of liability is not allowed in full or in part, this limitation may not apply to You.**
- c. The disclaimer of warranties and limitation of liability provided above shall be interpreted in a manner that, to the extent possible, most closely approximates an absolute disclaimer and waiver of all liability.

Section 6 – Term and Termination.

- a. This Public License applies for the term of the Copyright and Similar Rights licensed here. However, if You fail to comply with this Public License, then Your rights under this Public License terminate automatically.
- b. Where Your right to use the Licensed Material has terminated under Section 6(a), it reinstates:
 1. automatically as of the date the violation is cured, provided it is cured within 30 days of Your discovery of the violation; or
 2. upon express reinstatement by the Licensor.

For the avoidance of doubt, this Section 6(b) does not affect any right the Licensor may have to seek remedies for Your violations of this Public License.

- c. For the avoidance of doubt, the Licensor may also offer the Licensed Material under separate terms or conditions or stop distributing the Licensed Material at any time; however, doing so will not terminate this Public License.
- d. Sections 1, 5, 6, 7, and 8 survive termination of this Public License.

Section 7 – Other Terms and Conditions.

- a. The Licensor shall not be bound by any additional or different terms or conditions communicated by You unless expressly agreed.
- b. Any arrangements, understandings, or agreements regarding the Licensed Material not stated herein are separate from and independent of the terms and conditions of this Public License.

Section 8 – Interpretation.

- a. For the avoidance of doubt, this Public License does not, and shall not be interpreted to, reduce, limit, restrict, or impose conditions on any use of the Licensed Material that could lawfully be made without permission under this Public License.
- b. To the extent possible, if any provision of this Public License is deemed unenforceable, it shall be automatically reformed to the minimum extent necessary to make it enforceable. If the provision cannot be reformed, it shall be severed from this Public License without affecting the enforceability of the remaining terms and conditions.
- c. No term or condition of this Public License will be waived and no failure to comply consented to unless expressly agreed to by the Licensor.
- d. Nothing in this Public License constitutes or may be interpreted as a limitation upon, or waiver of, any privileges and immunities that apply to the Licensor or You, including from the legal processes of any jurisdiction or authority.

Creative Commons is not a party to its public licenses. Notwithstanding, Creative Commons may elect to apply one of its public licenses to material it publishes and in those instances will be considered the “Licensor.” Except for the limited purpose of indicating that material is shared under a Creative Commons public license or as otherwise permitted by the Creative Commons policies published at creativecommons.org/policies, Creative Commons does not authorize the use of the trademark “Creative Commons” or any other trademark or logo of Creative Commons without its prior written consent including, without limitation, in connection with any unauthorized modifications to any of its public licenses or any other arrangements, understandings, or agreements concerning use of licensed material. For the avoidance of doubt, this paragraph does not form part of the public licenses.

Creative Commons may be contacted at creativecommons.org

Clinical Safety Licensing

Digital Technology Assessment Criteria (DTAC)

DTAC Assessment Document

This DTAC assessment is based on the template downloaded from the [NHS England Transformation Directorate website](#).

As part of our effort to use modern web standards and publish documents more openly, we have converted the .odt original document into a native web page in our documentation site.

DTAC Document

The assessment criteria is made up of five core components. Sections A and B will provide the assessors the context required to understand your product and support your evidence. The core assessment criteria is defined in section C1-C4. Section D details the key Usability and Accessibility principles required. Further frequently asked questions are available at the end of the document.

The core criteria in Section C will determine the overall success of the assessment of your product or service. The accompanying score provided from Section D will show the level of adherence to the NHS Service Standard.

Section A. Company information

Non-assessed section

Information about your organisation and contact details.

Code	Question	Response
A1	Provide the name of your company	Royal College of Paediatrics and Child Health (RCPCH)
A2	Provide the name of your product	RCPCH Digital Growth Charts
A3	Provide the type of product	Digital Growth Charts Application Programming Interface and related tools and platform
A4	Provide the name and job title of the individual who will be the key contact at your organisation	Richard Burley - Chief Digital Officer
A5	Provide the key contact's email address	richard.burley@rcpch.ac.uk
A6	Provide the key contact's phone number	020 70926037
A7	Provide the registered address of your company	5-11, Theobalds Rd, London WC1X 8SH, United Kingdom
A8	In which country is your organisation registered?	England, Wales and Scotland
A9	If you have a Companies House registration in the UK please provide your number	A Registered Charity in England and Wales (1057744) and in Scotland (SC038299)

Code	Question	Response
A10	If applicable, when was your last assessment from the Care Quality Commission (CQC)?	Not applicable
A11	If applicable, provide your latest CQC report.	N/A

Section B. Value proposition

Non-assessed section

Please set out the context of the clinical, economic or behavioural benefits of your product to support the review of your technology. This criteria will not be scored but will provide the context of the product undergoing assessment.

Where possible, please provide details relating to the specific technology and not generally to your organisation.

Code	Question	Options	Response
B1	Who is this product intended to be used for?	Patients Diagnostics Clinical Support Infrastructure Workforce Other	<p>Diagnostics/Clinical Support</p> <p>This product is used by a range of health care professionals (GPs, paediatricians, nurses, health visitors, midwives, school nurses) to evaluate and record a child's growth.</p>
B2	Provide a clear description of what the product is designed to do and of how it is expected to be used	Free text	<p>The RCPCH Digital Growth Charts API provides reliable growth calculation for children of all ages capturing sex, DOB, weight, length, head circumference and BMI, for the range of 23 weeks premature to 20 years old for standard charts, and also provides Turner Syndrome and Down Syndrome calculations.</p> <p>The product allows the returned structured data to be displayed in a number of different ways depending on the clinician's needs, and for the data to be saved, charted, and trended within Electronic Patient Record systems. This richly functional solution with features such as automatic gestational age correction, bone age, mid-parental height, event recording, and specialist references is designed to bring high-quality growth parameter calculations to clinicians at the point of care.</p>

Code	Question	Options	Response
B3	Describe clearly the intended or proven benefits for users and confirm if / how the benefits have been validated	Free text	<ul style="list-style-type: none"> • Produced by a multidisciplinary group of members and other experts from clinical paediatrics, health informatics, statistics and programming, as well as childhood growth and nutrition specialists, health visitors and information governance experts. • Access includes RCPCH-created guidelines and advice for health professionals aiming to improve standards of growth measurement and assessment. • API returns structured data, and recommended SNOMED -CT clinical terminology. • Easy creation of apps and interfaces that will give clinicians accurate data to improve care and give access to their children's growth records online. • Access to ongoing maintenance and future development. • The ability to receive longitudinal growth data of individual children, which will enable the API to map children's growth pattern, trajectory and thrive lines. • Standardised open data format for all growth references, allowing research groups to develop specialist or localised growth charts using third party dataset. • Registered with the Medicines and Healthcare Products Regulatory Agency as a UKCA marked Medical Device. • Provision of the Clinical Standard Service Level Agreement, i.e., provision of support from 9am to 5pm, Monday to Friday.
B4	<p>Please attach one or more user journeys which were used in the development of this product</p> <p>Where possible please also provide your data flows</p>	Provided Not available	<p>User journeys are provided on our documentation website.</p> <p>https://growth.rcpch.ac.uk</p>

Section C. Technical questions

Assessed sections

C1 - Clinical safety

Establishing that your product is clinically safe to use.

You must provide responses and documentation relating to the specific technology product that is subject to assessment.

The DCB0129 standard applies to organisations that are responsible for the development and maintenance of health IT systems. A health IT system is defined as “product used to provide electronic information for health and social care purposes”. DTAC is designed as the assessment criteria for digital health technologies and C1 Clinical Safety Criteria is intended to be applied to all assessments. If a developer considers that the C1 Clinical Safety is not applicable to the product being assessed, rationale must be submitted exceptionally detailing why DCB0129 does not apply.

The DCB0160 standard applies to the organisation in which the health IT is deployed or used. It is a requirement of the standard (2.5.1) that in the procurement of health IT systems the organisation must ensure that the manufacturer and health IT system complies with DCB0129. The organisation must do so in accordance with the requirements and obligations set out in the DCB0160 standard. This includes personnel having the knowledge, experience and competences appropriate to undertaking the clinical risk management tasks assigned to them and organisations should ensure that this is the case when assessing this section of the DTAC.

If the Clinical Safety Officer or any other individual has concerns relating to safety of a medical device including software and apps, this should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting system:

[Report a problem with a medicine or medical device - GOV.UK \(www.gov.uk\)](https://www.gov.uk/report-a-problem-with-a-medicine-or-medical-device).

Code	Question	Options	Supporting information	Response
C1.1	Have you undertaken Clinical Risk Management activities for this product which comply with DCB0129?	Yes No	The DCB0129 standard applies to organisations that are responsible for the development and maintenance of health IT systems. A health IT system is defined as "a product used to provide electronic information for health and social care purposes".	Yes
C1.1.1	Please detail your clinical risk management system	Provided No evidence available	DCB0129 sets out the activities that must and should be undertaken for health IT systems. An example clinical risk management system template can be downloaded from the NHS Digital website.	Provided. All details of the Clinical Risk Management System in place at RCPCH Digital Growth Charts are held on our public documentation site at https://growth.rcpch.ac.uk/safety/overview/

Code	Question	Options	Supporting information	Response
C1.1.2	Please supply your Clinical Safety Case Report and Hazard Log	Provided No evidence available	<p>Specifically, your DTAC submission should include:</p> <ul style="list-style-type: none"> • A summary of the product and its intended use • A summary of clinical risk management activities • A summary of hazards identified which you have been unable to mitigate to as low as it is reasonably practicable • The clear identification of hazards which will require user or commissioner action to reach acceptable mitigation (for example, training and business process change) <p>It should not include the hazard log in the body of the document - this should be supplied separately.</p> <p>Example Clinical Safety Case Report and Hazard Log templates can be downloaded from the NHS Digital website.</p>	<p>Provided.</p> <p>Clinical Safety Case Report:</p> <p>https://growth.rcpch.ac.uk/safety/csmf/clinical-safety-case-report/</p> <p>Hazard Log:</p> <p>https://growth.rcpch.ac.uk/safety/csmf/hazard-log/</p>
C1.2	Please provide the name of your Clinical Safety Officer (CSO), their profession and registration details	Free Text	<p>The CSO must:</p> <ul style="list-style-type: none"> • Be a suitably qualified and experienced clinician • Hold a current registration with an appropriate professional body relevant to their training and experience • Be knowledgeable in risk management and its application to clinical domains • Be suitably trained and qualified in risk management or have an understanding in principles of risk and safety as applied to Health IT • Have completed appropriate training <p>The work of the CSO can be undertaken by an outsourced third party.</p>	<p>Dr Marcus Baw</p> <p>GMC: 4712729</p> <p>General Practitioner</p> <p>Software Developer</p> <p>NHS Digital Trained Clinical Safety Officer</p>

Code	Question	Options	Supporting information	Response
C1.3	If your product falls within the UK Medical Devices Regulations 2002, is it registered with the Medicines and Healthcare products Regulatory Agency (MHRA)?	Yes No Not applicable	<p>If this question is not applicable, because your product does not fall within the UK Medical Devices Regulations 2002, continue to question C1.4.</p> <p>If No, but the product falls within the UK Medical Devices Regulations 2002, continue to question C.1.3.2.</p> <p>The MHRA provides guidance on medical devices to place them on the market in Great Britain and Northern Ireland, regulatory requirements for all medical devices to be placed on the UK market, conformity assessment and the UK Conformity Assessed (UKCA) mark, classification of stand-alone medical device software (including apps) and how to tell if your product falls within the UK Medical Devices Regulations 2002.</p>	<p>Yes, the RCPCH Digital Growth Charts API is registered as a Class I Medical Device with the MHRA.</p> <p>Our GMDN Term is 65712 - Paediatric growth calculation API software</p>
C1.3.1	If yes, please provide your MHRA registration number	Free text		<p>MHRA Account Number 13251</p> <p>Digital Growth Charts Device Application reference 2022020401237576</p>
C1.3.2	If the UK Medical Device Regulations 2002 are applicable, please provide your Declaration of Conformity and, if applicable, certificate of conformity issued by a Notified Body / UK Approved Body	Provided No evidence available	<p>Medical device manufacturers must ensure that their device complies with the relevant Essential Requirements of the legislation and draw up a Declaration of Conformity to declare this.</p> <p>Class I devices with a measuring function and devices in Class IIa, IIb and III must undergo conformity assessment from an EU Notified Body or UK Approved Body which has been designated for medical devices, and be issued a certificate of conformity (commonly referred to as a “CE certificate” or “UKCA certificate”</p>	<p>Provided.</p> <p>https://growth.rcpch.ac.uk/safety/medical-device-reg/doc-api/</p> <p>As a Class I Medical Device there is no requirement for Notified Body / UK Approved Body certificate of conformity.</p>
C1.4	Do you use or connect to any third-party products?	Yes No	<p>If no, continue to section C2.</p> <p>DCB0129 contains the requirements in relation to third party products.</p>	No

Code	Question	Options	Supporting information	Response
C1.4.1	If yes, please attach relevant Clinical Risk Management documentation and conformity certificate	Provided No evidence available		Not applicable

C2 - Data protection

Establishing that your product collects, stores and uses data (including personally identifiable data) compliantly.

This section applies to the majority of digital health technology products however there may be some products that do not process any NHS held patient data or any identifiable data. If this is the case, the Data Protection Officer, or other suitably authorised individual should authorise this data protection section being omitted from the assessment.

Code	Question	Options	Supporting information	Response
C2.1	<p>If you are required to register with the Information Commissioner, please attach evidence of a current registration.</p> <p>If you are not required to register, please attach a completed self-assessment showing the outcome from the Information Commissioner and your responses which support this determination.</p>	Provided Not provided	<p>There are some instances where organisations are not required to register with the Information Commissioner. This includes where no personal information is being processed.</p> <p>The Information Commissioner has a registration self-assessment tool to support this decision making.</p>	<p>Provided.</p> <p>The RCPCH has ICO Registration, registration number: Z5143673</p>

Code	Question	Options	Supporting information	Response
C2.2	Do you have a nominated Data Protection Officer (DPO)?	Yes No We do not need one	<p>Not all organisations are required to have a Data Protection Officer (DPO). This is determined by the type of organisation and core activities. The most common reason for organisations providing digital health technologies to have a DPO is due to the core activities involving processing health data (being a special category).</p> <p>The Information Commissioner has a self-assessment tool to determine whether you must appoint a DPO.</p>	Yes.
C2.2.1	<p>If you are required to have a nominated Data Protection Officer, please provide their name.</p> <p>If you are not required to have a DPO please attach a completed self-assessment showing the outcome from the Information Commissioner and your responses which support this determination.</p>	Free text Provided		<p>Adele Picken</p> <p>RCPCH Head of Information Governance</p> <p>Tel. 020 7092 6030</p>
C2.3	Does your product have access to any personally identifiable data or NHS held patient data?	Yes No	<p>The UK General Data Protection Regulation (GDPR) applies to the processing of personal data.</p> <p>If no, continue to question C2.4</p>	No

Code	Question	Options	Supporting information	Response
C2.3.1	<p>Please confirm you are compliant (having standards met or exceeded status) with the annual Data Security and Protection Toolkit Assessment.</p> <p>If you have not completed the current year's assessment and the deadline has not yet passed, please confirm that you intend to complete this ahead of the deadline and that there are no material changes from your previous years submission that would affect your compliance.</p>	Confirmed Unable to confirm	The Data Security and Protection Toolkit allows organisations to measure performance against the National Data Guardian's 10 data security standards.	<p>Confirmed.</p> <p>Standards Exceeded.</p> <p>https://www.dsptoolkit.nhs.uk/OrganisationSearch/8HV48</p>
C2.3.2	Please attach the Data Protection Impact Assessment (DPIA) relating to the product.	Provided Not provided	<p>DPIAs are a key part of the accountability obligations under the UK GDPR, and when done properly help organisations assess and demonstrate how they comply with data protection obligations.</p> <p>The Information Commissioner has provided guidance on how to complete a DPIA and a sample DPIA template.</p>	<p>The RCPCH used the ICO DPIA Checklist to determine if a DPIA was required and the outcome was that a DPIA was NOT required on the basis that personally identifiable data is not handled.</p> <p>The information submitted does not identify the individual on its own. RCPCH also does not have access to the information nor stores. RCPCH does not use the information to learn, record or decide anything about the data subject. RCPCH is not data controller of this information. The healthcare organization using the tool, as data controller of the data being provided, may be required to undertake a DPIA but this will depend on their own assessment. We have consulted with our Data Protection Officer on all matters of data protection and have their agreement.</p>

Code	Question	Options	Supporting information	Response
C2.4	Please confirm your risk assessments and mitigations / access controls / system level security policies have been signed-off by your Data Protection Officer (if one is in place) or an accountable officer where exempt in question C2.2.	Confirm Cannot confirm		Confirm.
C2.5	Please confirm where you store and process data (including any third-party products your product uses)	UK only In EU Outside of EU	Individual organisations within the Health and Social Care system are accountable for the risk-based decisions that they must take.	UK Only (London, England)
C2.5.1	If you process store or process data outside of the UK, please name the country and set out how the arrangements are compliant with current legislation	Free text	<p>From 1 January 2021, the UK GDPR applies in the UK in place of the "EU GDPR". The UK GDPR will carry across much of the existing EU GDPR legislation. The Department for Digital, Culture, Media & Sport has published two Keeling Schedules which show the changes to the Data Protection Act 2019 and EU GDPR.</p> <p>The Information Commissioner has published guidance on international data transfers after the UK exit from the EU Implementation Period.</p>	Not applicable. All data is processed in the UK.

C3 - Technical security

Establishing that your product meets industry best practice security standards and that the product is stable.

Dependent on the digital health technology being procured, it is recommended that appropriate contractual arrangements are put in place for problem identification and resolution, incident management and response planning and disaster recovery.

Please provide details relating to the specific technology and not generally to your organisation.

Code	Question	Options	Supporting information	Response
C3.1	Please attach your Cyber Essentials Certificate	Provided No evidence available	Cyber Essentials helps organisations guard against the most common cyber threats. The National Cyber Security Centre (NCSC) have published cyber security guidance for small to medium enterprises (SME's).	Our Cyber Essentials certificate is published here https://growth.rcpch.ac.uk/technical/security/#cyber-essentials
C3.2	Please provide the summary report of an external penetration test of the product that included Open Web Application Security Project (OWASP) Top 10 vulnerabilities from within the previous 12-month period.	Provided No evidence available	The NCSC provides guidance on penetration testing . The OWASP Foundation provides guidance on the OWASP top 10 vulnerabilities .	Penetration testing is in the process of being conducted. Evidence from this is to be provided.
C3.3	Please confirm whether all custom code had a security review.	Yes - Internal code review Yes - External code review No No because there is no custom code	The NCSC provides guidance on producing clean and maintainable code .	Yes - Internal code review
C3.4	Please confirm whether all privileged accounts have appropriate Multi-Factor Authentication (MFA)?	Yes No	The NCSC provides guidance on Multi-Factor Authentication .	Yes.

Code	Question	Options	Supporting information	Response
C3.5	Please confirm whether logging and reporting requirements have been clearly defined.	Yes No	<p>The NCSC provides guidance on logging and protective monitoring.</p> <p>To confirm yes to this question, logging (e.g., audit trails of all access) must be in place. It is acknowledged that not all developers will have advanced audit capabilities.</p>	Yes.
C3.6	Please confirm whether the product has been load tested	Yes No	Load testing should be performed.	Yes.

C4 - Interoperability criteria

Establishing how well your product exchanges data with other systems.

To provide a seamless care journey, it is important that relevant technologies in the health and social care system are interoperable, in terms of hardware, software and the data contained within. For example, it is important that data from a patient's ambulatory blood glucose monitor can be downloaded onto an appropriate clinical system without being restricted to one type. Those technologies that need to interface within clinical record systems must also be interoperable. Application Programme Interfaces (APIs) should follow the Government Digital Services Open API Best Practices, be documented and freely available and third parties should have reasonable access in order to integrate technologies.

Good interoperability reduces expenditure, complexity and delivery times on local system integration projects by standardising technology and interface specifications and simplifying integration. It allows it to be replicated and scaled up and opens the market for innovation by defining the standards to develop upfront.

This section should be tailored to the specific use case of the product and the needs of the buyer however it should reflect the standards used within the NHS and social care and direction of travel.

Please provide details relating to the specific technology and not generally to your organisation.

Code	Question	Options	Supporting information	Response
C4.1	Does your product expose any Application Programme Interfaces (API) or integration channels for other consumers?	Yes No	The NHS website developer portal provides guidance on APIs and the NHS . Government Digital Services provide guidance on Open API best practice .	Yes.
C4.1.1	<p>If yes, please provide detail and evidence:</p> <ul style="list-style-type: none"> • The API's (e.g., what they connect to) set out the healthcare standards of data interoperability e.g. Health Level Seven International (HL7) / Fast Healthcare Interoperability Resources (FHIR) • Confirm that they follow Government Digital Services Open API Best Practice • Confirm they are documented and freely available • Third parties have reasonable access to connect <p>If no, please set out why your product does not have APIs.</p>	Free text		<p>Our product is entirely designed to be interoperable and our primary offering is a Digital Growth Charts API which is interoperable.</p> <p>Our API and ancillary development toolkits are fully documented at our public documentation site at https://growth.rcpch.ac.uk/</p> <p>API documentation is in the international OpenAPI3 documentation standard.</p> <p>Government Digital Services Open API Best Practice is followed throughout.</p> <p>Connection to third parties is our intended business model as we actively encourage connection and full integration, providing both free access at lower levels of usage, and supported enterprise integration support.</p>
C4.2	Do you use NHS number to identify patient record data?	Yes No No, because product does not identify patient record data	NHS Digital provides guidance on NHS Login for partners and developers .	No, because product does not identify patient record data

Code	Question	Options	Supporting information	Response
C4.2.1	If yes, please confirm whether it uses NHS Login to establish a user's verified NHS number. If no, please set out the rationale, how your product established NHS number and the associated security measures in place.	Free text		N/A
C4.3	Does your product have the capability for read/write operations with electronic health records (EHRs) using industry standards for secure interoperability (e.g. OAuth 2.0, TLS 1.2)	Yes No No, because the product does not read/ write into EHRs		No, because the product does not read/ write into EHRs
C4.3.1	If yes, please detail the standard	Free text		
C4.3.2	If no, please state the reasons and mitigations, methodology and security measures.	Free text		
C4.4	Is your product a wearable or device, or does it integrate with them?	Yes No	If no, continue to section D.	No
C4.4.1	If yes, provide evidence of how it complies with ISO/IEEE 11073 Personal Health Data (PHD) Standards.	Provided No evidence available	Access the ISO Standard . This is a paid-for document.	

Section D. Key principles for success

The core elements defined in this section will form part of the overall review of the product or service and is a key part to ensuring that the product or service is suitable for use. The assessment will set a compliance rating and where a product or developer is not compliant highlight areas that the organisation could improve on with regards to following the core principles.

This section will be scored in relation to the [NHS service standard](#). This will not contribute to the overall Assessment Criteria as set out in Section C.

D1 - Usability and accessibility

scored section

Establishing that your product has followed best practice.

Please note that not all sections of the [NHS Service Standard](#) are included where they are assessed elsewhere within [DTAC](#), for example clinical safety.

Code	Question	Options	Supporting information	Weighted score	Scoring criteria
D1.1	<p>Understand users and their needs in context of health and social care</p> <p>Do you engage users in the development of the product?</p>	Yes No Working towards it	NHS Service Standard Point 1	0%	<p>Yes.</p> <p>User needs are continually integrated into the development workflow.</p> <p>The user needs of Paediatricians, nurses and other clinical staff are represented by the Digital Growth Charts Project Board, which is composed of nominated user representatives</p> <p>https://growth.rcpch.ac.uk/about/team/#project-board</p> <p>Additionally we have open Issue reporting which allows anyone, whether user, patient, or parent/ carer to report a user need or requirement for consideration by the development team.</p>
D1.1.1	If yes or working towards it, how frequently do you consider user needs in your product development and what methods do you use to engage users and understand their needs?	text			<p>User needs are constantly re-evaluated and are a central part of our development workflow. New user needs can be incorporated into our 2-weekly development cycles quite easily and new deployments of improved platform features can be achieved rapidly</p>
D1.2	<p>Work towards solving a whole problem for users</p> <p>Are all key user journeys mapped to ensure that the whole user problem is solved, or it is clear to users how it fits into their pathway or journey?</p>	Yes No Working towards it	NHS Service Standard Point 2 and Point 3 are often dealt with by teams together.	0%	User journeys to follow

Code	Question	Options	Supporting information	Weighted score	Scoring criteria
D1.2.1	If yes or working towards it, please attach the user journeys and/or how the product fits into a user pathway or journey	Provided No evidence available			
D1.3	<p>Make the service simple to use</p> <p>Do you undertake user acceptance testing to validate usability of the system?</p>	Yes No Working towards it	NHS Service Standard Point 4	0%	<p>No.</p> <p>The product we provide is a toolkit and API which is integrated into EHRs by our customers (the EHR suppliers). Our toolkit does not <i>in itself</i> have users.</p> <p>Those EHR suppliers perform their own UAT on their implementation of our toolkit and API, to validate usability of their system.</p> <p>If a supplier found a usability issue which originated within our toolkit or API they would escalate this back to us for action.</p>
D1.3.1	If yes or working towards it, please attach information that demonstrates that user acceptance testing is in place to validate usability.	Provided No evidence available			N/A

Code	Question	Options	Supporting information	Weighted score	Scoring criteria
D1.4	<p>Make sure everyone can use the service</p> <p>Are you international Web Content Accessibility Guidelines (WCAG) 2.1 level AA compliant?</p>	Yes No Working towards it	<p>a href="https://service-manual.nhs.uk/service-standard/5-make-sure-everyone-can-use-the-service">NHS Service Standard Point 5</p> <p>The Service Manual provides information on WCAG 2.1 level AA.</p> <p>The Government Digital Service provides guidance on accessibility and accessibility statements, including a sample template.</p>	0%	Yes.
D1.4.1	Provide a link to your published accessibility statement.	Free text		0%	https://growth.rcpch.ac.uk/
D1.5	<p>Create a team that includes multi-disciplinary skills and perspectives</p> <p>Does your team contain multidisciplinary skills?</p>	Yes No Working towards it	<p><a >nhs="" 6<="" a="" href="https://service-manual.nhs.uk/service-standard/6-create-a-team-that-includes-multidisciplinary-skills-and-perspectives" point="" service="" standard=""></p>	2.5%	Yes.
D1.6	<p>Use agile ways of working</p> <p>Do you use agile ways of working to deliver your product?</p>	Yes No Working towards it	<p><a >nhs="" 7<="" a="" href="https://service-manual.nhs.uk/service-standard/7-use-agile-ways-of-working" point="" service="" standard=""></p>	2.5%	Yes.
D1.7	<p>Iterate and improve frequently</p> <p>Do you continuously develop your product?</p>	Yes No Working towards it	<p><a >nhs="" 8<="" a="" href="https://service-manual.nhs.uk/service-standard/8-iterate-and-improve-frequently" point="" service="" standard=""></p>	%	Yes.

Code	Question	Options	Supporting information	Weighted score	Scoring criteria
D1.8	<p>Define what success looks like and be open about how your service is performing</p> <p>Do you have a benefits case that includes your objectives and the benefits you will be measuring and have metrics that you are tracking?</p>	Yes No Working towards it	NHS Service Standard Point 10	0%	Yes.
D1.9	<p>Choose the right tools and technology</p> <p>Does this product meet with NHS Cloud First Strategy?</p>	Yes No No because it is not applicable	https://service-manual.nhs.uk/service-standard/11-choose-the-right-tools-and-technology >NHS Service Standard Point 11 NHS Internet First Policy.	%	Yes. Yes.
D1.9.1	Does this product meet the NHS Internet First Policy?	es No No because it is not applicable			
D1.10	<p>Use and contribute to open standards, common components and patterns</p> <p>Are common components and patterns in use?</p>	Yes No Working towards it	NHS Service Standard Point 13	%	Yes.

Code	Question	Options	Supporting information	Weighted score	Scoring criteria
D1.10.1	If yes, which common components and patterns have been used?	Free text			Microsoft Azure API Management Platform FastAPI framework React.js Semantic UI Python SNOMED-CT
D1.11	Operate a reliable service Do you provide a Service Level Agreement to all customers purchasing the product?	es No	NHS Service Standard Point 14	0%	Yes.
D1.12	Do you report to customers on your performance with respect to support, system performance (response times) and availability (uptime) at a frequency required by your customers?	es No			Yes. A public uptime monitor is always visible on our documentation site https://growth.rcpch.ac.uk/technical/status
D1.12.1	Please attach a copy of the information provided to customers	Provided No evidence available			Provided (SLA)
D1.12.2	Please provide your average service availability for the past 12 months, as a percentage to two decimal places	Free text			Last 90 days 99.839% uptime. Information for last 12 months is not yet available.

Supporting documentation

Please ensure that when providing evidence, documents are clearly labelled with the name of your company, the question number and the date of submission.

Possible documents to be provided are:

- A11 - CQC Report
- B4 - User journeys and data flows
- C1.1.1 - Clinical Risk Management System
- C1.1.2 - Clinical Safety Case Report
- C1.1.2 - Hazard Log
- C1.3.2 - UK Medical Device Regulations 2002 Declaration of Conformity and if applicable Certificate of Conformity
- C1.4.1 - Clinical Risk Management documentation and Conformity certificate for third party suppliers
- C2.1 - Information Commissioner's registration or completed Self-assessment Outcome Tool
- C2.2.1 Completed Information Commissioner's Self-Assessment Outcome Tool
- C2.3.2 - Data Protection Impact Assessment (DPIA)
- C3.1 - Cyber Essentials Certification
- C3.2 - External Penetration Test Summary Report
- C4.4.1 - If a wearable, evidence of how the product complies with ISO/IEEE 11073 Personal Health Data (PHD) Standards
- D1.2.1 - User Journeys and/or how the product fits into a user pathway or journey
- D1.3.1 - Supporting information showing user acceptance testing to validate usability
- D1.13.2 - Customer Performance Report

Document origin

Based on the OpenDocument version of the Digital Technology Assessment Criteria for Health and Social Care (DTAC), Version 1.0 22 February 2021, last updated 16th April 2021. RCPCH responses are in bold type.

DTAC Clinical Safety

UK Medical Device Registration

The Digital Growth Charts API server and associated user interface libraries (together termed the RCPCH dGC Platform) are a Medical Device as determined under the [Medical Devices Regulations 2002](#), Regulation 2 (1) "medical device" (a) (i) in that it "is intended by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease".

MHRA Medical Device Registration and GMDN Nomenclature



The RCPCH Digital Growth Charts API is registered with the MHRA as a Class I medical device, with the GMDN Identifier of [65712 - Paediatric growth calculation API software](#)

Determination of Medical Device Class

Determination of the class of medical device applicable was performed using the [MHRA Medical Device Class tool](#) on 7th May 2021 by Dr Marcus Baw, with reference to relevant supporting documents and legislation.

Post Market Surveillance

- User/API key registry enables communication with each implementer
- Forum
- Email list

UK Responsible Person

- [Information of Responsible Persons](#)

Medical Device Regulation

MHRA Essential Requirements

MHRA Medical device essential requirements - general

This is the reference standard which we used as a starting point in assuring safety and quality when developing the Digital Growth Charts.

The following apply to all devices

- The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of the patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. This shall include
 - reducing as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and
 - consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).
- The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order
 1. eliminate or reduce risks as far as possible (inherently safe design and construction),
 2. where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,
 3. inform users of the residual risks due to any shortcomings of the protection measures adopted.
- The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in UK MDR 2002 - Part I Section 2(1), as specified by the manufacturer.
- The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.
- The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.
- Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.

6a. Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.

Design and construction essential requirements

The manufacturer will need to determine which apply to their software by reviewing Regulation 9 of UK MDR 2002. The following are likely to apply to software devices:

9.1 If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use.

12.1 Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.

12.1a For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.

12.4 Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm system to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.

12.9.1 Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.

13.1 Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer.

This information comprises the details on the label and the data in the instructions for use

13.3 The label must bear the following particulars.

13.6 Where appropriate, the instructions for use must contain the following particulars:

(c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination;

d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times;

The following are possibly applicable to software devices

10.1. Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer.

10.2. The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.

10.3. The measurements made by devices with a measuring function must be expressed in legal units conforming to the Units of Measurement Regulations 1986.

Medical Device Regulation

Declaration of Conformity (API Server)

EU DECLARATION OF CONFORMITY

1. Unique identification of the product

The Royal College of Paediatrics and Child Health Digital Growth Charts Application Programming Interface **Server**, all versions. <https://github.com/rcpch/digital-growth-charts-server>

1. Name and address of the manufacturer or his authorised representative

The Royal College of Paediatrics and Child Health (RCPCH), 5-11 Theobalds Road, London, WC1X 8SH (telephone: +44 (0)20 7092 6000).

1. This declaration of conformity is issued under the sole responsibility of the manufacturer (or installer)

The Royal College of Paediatrics and Child Health (RCPCH)

1. Object of the declaration (identification of product allowing traceability. It may include a colour image of sufficient clarity to enable the identification of the product, where appropriate.)

There is no image, this is an entirely software product, with no dedicated hardware.

Server application code is located at <https://github.com/rcpch/digital-growth-charts-server>

1. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation

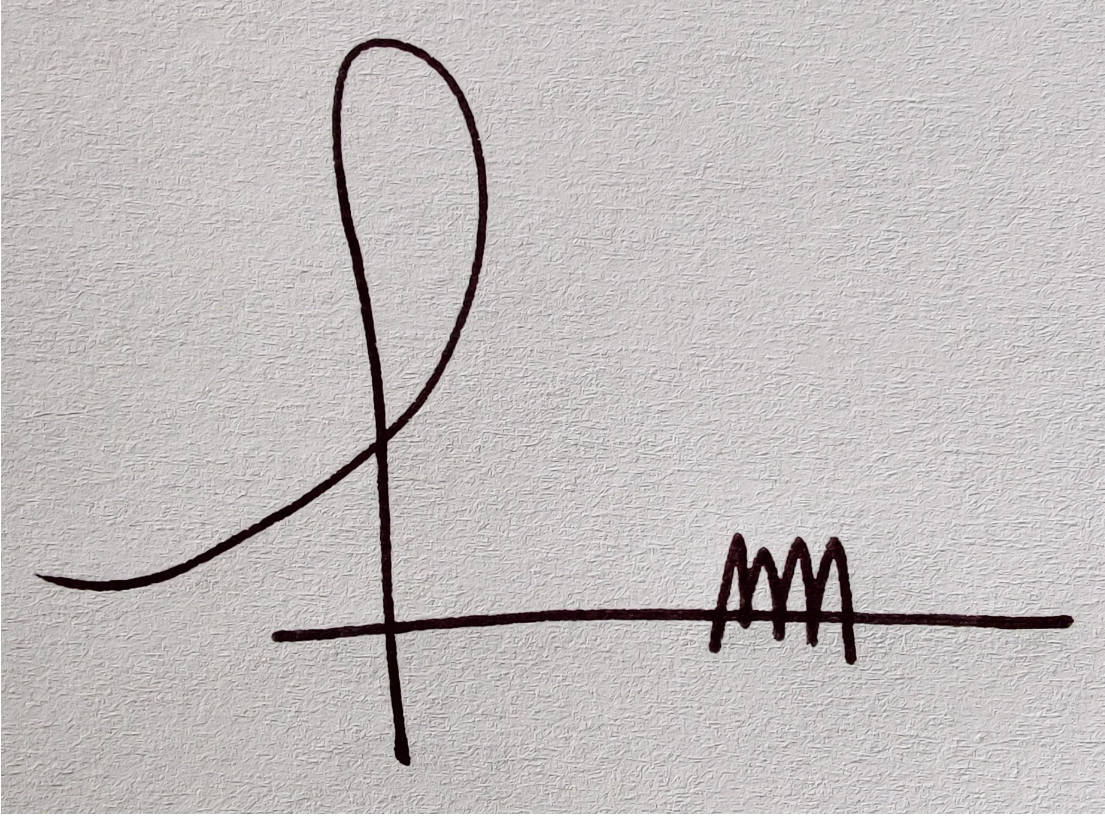
2. Regulation (EU) 2017/745 - Medical Devices

3. References to the relevant harmonised standards used, or references to the specifications in relation to which conformity is declared

4. Technical file

The complete unabridged technical file, all documentation, instructions for use, and the application source code itself are available publicly within this [RCPCH dGC documentation site](#) and the GitHub repository <https://github.com/rcpch/digital-growth-charts-server>.

Signed for and on behalf of	The Royal College of Paediatrics and Child Health
Place of Issue	Cawood, North Yorkshire, UK
Date of Issue	7th May 2021
Name	Dr Marcus Baw

Position	Lead Developer, Clinical Safety Officer, GP and EM Clinician.
Signature	

Medical Device Regulation

Technical Documentation for EU Medical Device Regulation

Digital Growth Charts Project

1. Your name and address, or those of any authorised representatives

The Royal College Of Paediatrics and Child Health (RCPCH), 5-11 Theobalds Road, London, WC1X 8SH (telephone: +44 (0)20 7092 6000).

1. A brief description of the product

A web-based software program which allows communication between user and/or back-end applications/databases (API - application programming interface) intended to assist a clinician by calculating variation in children's growth parameters [e.g., height, weight, head circumference, body mass index (BMI)] based on input data (e.g., birth height and weight, gender, gestation). The information may be used to detect children developing underweight or overweight, with height abnormalities or other related disorders.

1. Identification of the product, for example, the product's serial number

RCPCH Digital Growth Charts Platform, comprising of:

1. [The Digital Growth Charts API](#), which receives growth measurements and returns growth calculations.
2. [The React Chart Component](#), which takes the returned growth calculation JSON data and displays as a HTML-based RCPCH standard visual growth chart that is familiar to clinicians.
3. [The RCPCH Growth Python Library](#), which provides the calculation functionality within the API Server.

This documentation pertains to **all versions** of the product. Current latest versions can be viewed by consulting the relevant repository at the RCPCH GitHub organisation <https://github.com/rcpch>

1. The name(s) and address(es) of the facilities involved in the design and manufacture of the product

The product was designed and developed entirely remotely by a geographically dispersed team, and online using collaboration software such as Git, GitHub, Google Meet, Microsoft Teams, and Signal instant messaging.

The 'place of manufacture' of the product could be most accurately said to be the code collaboration platform [GitHub](#), and the primary tooling used in the manufacture was Microsoft Visual Studio Code.

1. **The name and address of any notified body involved in assessing the conformity of the product**

Not Applicable due to the Class I designation of the Device

1. **A statement of the conformity assessment procedure that has been followed**

Not Applicable due to the Class I designation of the Device

1. **The EU declaration of conformity**

See [Declaration of Conformity](#)

1. **Label and instructions of use**

All instructions for use are contained within [this documentation website](#).

1. **A statement of relevant regulations to which the product complies**

2. Regulation (EU) 2017/745 - Medical Devices

3. **Identification of technical standards with which compliance is claimed**

There are no technical standards pertaining directly to the manufacture of this kind of medical device.

1. **A list of parts**

2. **Compliant parts**

3. Digital Growth Charts Application Programming Interface **Server, Version 1**

4. Digital Growth Charts Application Programming Interface **React Charting Component, Version 1**

5. Digital Growth Charts Application Programming Interface **Demo React Client, Version 1**

6. Digital Growth Charts Application Programming Interface **Demo React Native Client, Version 1**

7. **Supplementary parts (for which compliance is not claimed)**

8. **Test results**

Automated tests on the programs are run on every code change. If the tests fail then the new code cannot be incorporated into the program, and the previous version will remain in place.

Tests can be viewed in the `test/` directory within each repository.

All repositories are listed at <https://github.com/rcpch>

Medical Device Regulation