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| GP Connect Provider Assurance Deliverables and Activities | | | |
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GP Connect Access Record Structured

Provider Assurance Deliverables and Activities

Document Management

Revision History

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| 0.1 | 25/06/2018 | Draft approach for Access Record Structured |
| 1.0 | 23/07/2018 | Updated and baselined following internal stakeholder comments |
| 2.0 | 25/03/2020 | Updated to accommodate the inclusion of the full clinical record |
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| 2.2 | 10/09/2020 | Changes document links to embedded icons |
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Reviewers

This document must be reviewed by the following people: author to indicate reviewers

|  |  |  |  |
| --- | --- | --- | --- |
| Reviewer name | Title / Responsibility | Date | Version |
| Matt Stephens | GP Connect Technical Architect |  | 2.2 |
| Martin Hillyard | GP Connect Business Analyst |  | 2.2 |
| Pete Salisbury | GP Connect Data Architect | ` | 2.2 |
| Neill Jones | GP Connect Clinician |  | 2.2 |
| Dr Rob Jeeves | GP Connect Clinician |  | 2.2 |
| Amit Chawla | Principal Practitioner - Solution Assurance |  | 2.2 |
| Zak Bickhan | Clinical Safety Officer |  | 2.2 |
| Hannah McCann | Clinical Safety Engineer |  | 2.2 |
| Peter Barrett | Information Assurance Analyst |  | 2.2 |
| Dan O’Neill | GP Connect Delivery Programme Manager |  | 2.2 |

Approved by

This document must be approved by the following people:

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Title | Date | Version |
| Amit Chawla | Principal Practitioner - Solution Assurance |  | 2.2 |
| Dan O’Neill | GP Connect – Delivery Programme Manager |  | 2.2 |

Glossary of Terms

|  |  |
| --- | --- |
| Term /Abbreviation | Definition |
| Provider | A software development company who supplies provider systems, principal clinical systems where the patient record is held |
| Consumer | The developer of an application that uses GP Connect FHIR API - for example, a system supplier in an acute or mental health care setting |
| DevMAC | Development Milestone Achievement Certificate |
| FOT | First of Type |
| FRA | Full Rollout Approval |
| CATR | Clinical Authority to Release |
| GPIT Futures | GPIT Futures Programme |
| GP Connect | The GP Connect Programme |
| API | Application Programming Interface |
| FHIR | Fast Healthcare interoperability Resources |
| IG | Information Governance |
| Github | GitHub is a Git repository hosting service, provides basic task management tools for projects. |
| RSD | Release Scope Definition |
| RFO | Ready for Operations |
| RFC | Request for Change |
| DBT | Design, Build, Test |
| EU General Data Protection Regulation (GDPR) | EU General Data Protection Regulation (GDPR) |
| DVC | Deployment Verification Criteria |
| DVP | Deployment Verification Period |
| CSG | Clinical Safety Group |
| SSP | Spine Server Proxy |

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# Overview

## 1.1 Purpose

This document sets out the GP Connect Provider Assurance Deliverables and Activities to be used by the Authority to assure the Access Record - Structured capability as delivered under the GPIT Futures framework

This document should be read in conjunction with the GP Connect Test Strategy for Providers, which outlines the test and assurance strategy for all GP Connect capabilities. Please contact gpconnect@nhs.net for the latest version.

# Scope

It should be noted that the term “Provider” is used throughout this document. This is used to describe any GP Clinical System suppliers that wish to develop against the Access Record Structured specification.

GP Connect aims to support better clinical care by enabling the sharing of data held in general practice, to agreed standards, for the purposes of direct care. The GP Connect scope includes the delivery of multiple capabilities through the provision of new API’s, within the Provider environments, in line with the API specifications and data standards (FHIR) provided by the Authority. This document outlines the assurance deliverables and activities which the Authority will use to assure one capability: Access Record – Structured. The assurance approach for other GP Connect capabilities will be documented separately.

The Access Record – Structured capability will provide access to a patients GP Record in a machine-readable format. The GP Connect scope will cover the following clinical areas; Medicines, Allergies, Consultations, Problems, Uncategorised, Immunisations, Investigations, Documents, Referrals and Diary entry

The current specifications for Access Record Structured can be found here:

<https://digital.nhs.uk/services/gp-connect/gp-connect-specifications-for-developers>

It should be noted that the assurance process, activities and deliverables covered in this document are only be relevant to the Provider API delivery. Consumer assurance will be managed via an alternative process.

## 2.1 Out of Scope

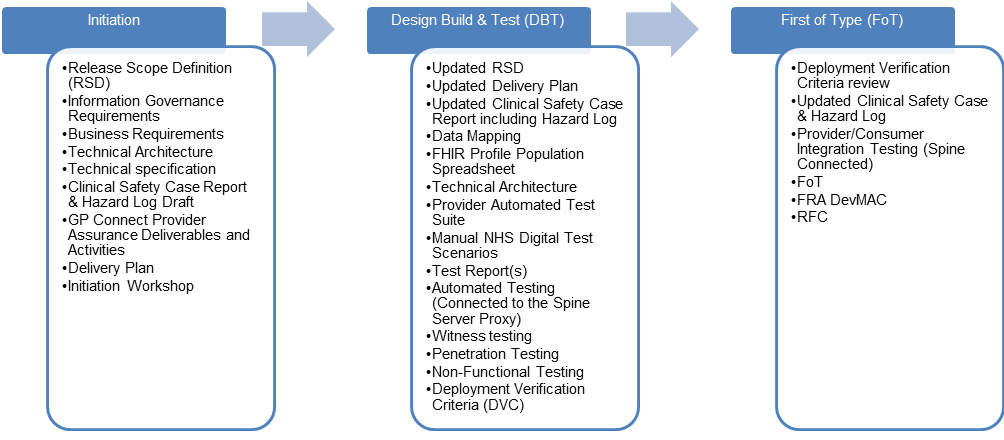
The assurance of the Consumer API components are not included within the scope of this assurance document. In addition, this document does not cover the Provider API assurance approach for other GP Connect capabilities (e.g. Access Record – HTML and Appointments Management).

# Approach to Clinical Assurance

Clinical assurance will comprise the following key stages:

* Clinically led testing will be undertaken to review the content of the message (the Payload) being sent from the Provider. For Access Record Structured – this is the data associated with the in-scope FHIR profiles. Test data will be created by both NHS Digital and the Provider. Following which NHS Digital will construct manual test scenarios. NHS Digital clinical team will agree the content of the test scenarios.
* Providers will deliver a Clinical Safety Case to NHS digital. This will describe a clinical view on the clinical safety and known hazards that exist within the delivered solution.
* Attendance at the Live Services Clinical Board – This is a Service led forum that will review the assurance that has been undertaken and the clinical safety case and hazard log that the Provider has created to make sure that Service are happy to accept the solution into the production environment.
* Attendance at the Clinical Safety Group – This is a clinically led forum that will review the assurance that has been undertaken and the clinical safety case and hazard log that the Provider has created to make sure that they are happy to accept the solution into the production environment.

# Assurance Stages



Assurance will follow 3 stages: Initiation, Design/Build/Test (DBT), and then First of Type (FOT). The deliverables and activities included within each stage are discussed below. A Provider must complete all stages before being allowed to make their product or service available for general use.

## 

## 4.1 Initiation Stage

**Overview**

Once a Provider has confirmed their interest in developing the GP Connect Appointments Management capability, NHS Digital will share the relevant documentation templates to enable them to complete necessary scoping work. NHS Digital will also set up an initial meeting to agree ways of working and the ongoing project governance structure

The Provider then completes the necessary documentation required to evidence to NHS Digital that they understand the product requirements and can explain how they are going to achieve delivery. Successful completion of these documents proves to NHS Digital that the provider:

* has understood the product scope and supporting infrastructure requirements
* has considered their delivery approach and have the skills required to deliver the solution
* has considered the IG and clinical safety requirements
* has understood the business requirements and how their product meets user needs

The following deliverables are required and expected to be submitted during the Initiation phase of the assurance process, for review. All documents must be submitted and reviewed prior to any Design, Build and Test activities.

|  |  |  |
| --- | --- | --- |
| Deliverable/Activity | Responsible | Approach |
| Technical Specification | NHS Digital | The Authority will provide a Technical Specification for the Access Record Structured capability. This document will include guidance for the Operational API Definition and FHIR Profile population. Specifications are available here.  - <https://digital.nhs.uk/services/gp-connect/gp-connect-specifications-for-developers> |
| Technical Architecture | Provider | The Provider will provide a draft document detailing the design of their technical architecture if this is different to what has been previously agreed for previous GP Connect implementations. |
| Business Requirements | NHS Digital | The Authority will provide a Requirements Catalogue which contains user scenarios, use cases and business requirements. This document is included in the specification.  <https://digital.nhs.uk/services/gp-connect/gp-connect-specifications-for-developers> |
| GP Connect Access Record Structured Provider Assurance Deliverables and Activities (this document) | NHS Digital | This document will be used to guide the assurance of the Provider solution and details all assurance deliverables and activities which must be completed to achieve successful sign-off of the release. It should be read in conjunction with the GP Connect Test Strategy for Providers |
| Release Scope Definition (RSD) | Provider | An RSD will be delivered by the Provider defining the scope of, and approach to this release. |
| Delivery Plan | Provider | The Provider will provide a plan defining the anticipated development approach and dates for when the deliverables will be submitted. |
| Clinical Safety Case Report & Hazard Log Draft | Provider | The Provider will produce a Clinical Safety Case Report that confirms that each of the hazard mitigations has been successfully implemented and risks mitigated to an acceptable level. The Clinical Safety Case Report should present a comprehensive case that the Provider remains adequately safe to deploy following implementation of the API. |
| Initiation Workshop | NHS Digital | An initiation workshop will be held to discuss appropriate ways of working and agree the approach to the assurance of this release, with the Provider and appropriate NHS Digital assurance stakeholders. |

**Milestones:**

Note. The Initiation Milestone Certificate will not be awarded.

These deliverables do not necessarily have to be signed off before the DBT commences.

## 4.2 Design Build and Test Phase

**Overview**

After the Initiation stage has completed, the Provider will move to the Design, Build and Test stage.

In the first instance, the GP Connect Project Manager will support the Provider during development. Technical Architects and Business Analysts will be available to provide expert knowledge for technical or business-related discussions.

Once the Provider has completed development, internal test evidence will need to be supplied to the NHS Digital Solution Assurance team. If the evidence is of an acceptable standard, there will be an agreement to commence formal assurance activities.

Upon successful completion of Solution Assurance activities, an email will be sent to the GP Connect Project Manager to confirm that the Provider has passed NHS Digital Solution Assurance test activities. This will be presented to the NHS Digital Clinical Safety Group (CSG) and the Live Services Clinical Board, alongside an updated Provider Clinical Safety Case and Hazard Log. If consent is given for the Provider solution to move into the next stage of testing, First of Type (FoT) assurance, a FoT DevMac including CATR (Clinical Authority to Release) will be awarded to the Provider by NHS Digital.

FoT DevMac is a milestone certificate confirming that the Provider solution can now be implemented to a small number of sites and tested in the Live Spine environment.

Parallel to the final stages of Solution Assurance activities, FoT preparation activities will commence between the GP Connect Project Manager, Provider and interested Consumer Supplier and FoT sites. As mentioned previously, the Consumer will have undertaken their own NHS Digital assurance activities.

Prior to FoT, NHS Digital will determine the Deployment Verification Criteria (DVC) which will be monitored during Deployment Verification Period (DVP). This includes Entry criteria and Exit criteria for FoT. The Entry criteria will be used as part of a Go/No Go call to confirm that FoT can begin. The Exit criteria will be used as evidence to confirm that FoT can close.

**Deliverables**

The following deliverables are required and expected to be submitted during the DB&T phase of the assurance process, for more information about these deliverables and the activities please see the GP Connect Test & Assurance Strategy for Providers:

| Deliverable/Activity | Responsible | Approach |
| --- | --- | --- |
| *Updated* RSD | Provider | The RSD should be updated where appropriate throughout assurance. |
| *Updated* Delivery Plan | Provider | The Delivery Plan be updated as and when required throughout assurance. |
| *Updated* Clinical Safety Case Report including Hazard Log | Provider | The Provider will update their Clinical Safety Case Report as and when required throughout assurance. |
| Technical Architecture | Provider | The Provider will provide the final document detailing the design of their technical architecture if this is different to what has been previously agreed for previous GP Connect implementations. |
| Provider Automated Test Suite | NHS Digital | NHS Digital will uplift the GP Connect Provider Automated Test Suite to incorporate validation tests for the Access Record – Structured capability. |
| Test Data | NHS Digital & Provider | NHS Digital and the Provider will work collaboratively to define a clinically rich test data set which will be used to formulate the manual/Clinical test scenarios. NHS Digital will provide a baseline or the test data for Provider to review. |
| Test Instance | Provider | The Provider will provide a test instance to support the Clinical test phase which will be populated with the above test data. |
| Provider Test Scenarios | Provider | The Provider must produce their own test scenarios to support their internal test activities  Refer to the document ‘GP Connect Test & Assurance Strategy for Providers’. |
| Manual NHS Digital Test Scenarios | NHS Digital | NHS Digital will produce manual test scenarios for the Provider to execute.  Refer to the document ‘GP Connect Test & Assurance Strategy for Providers’. |
| Test Report(s) | Provider | The Supplier will submit test report(s) detailing the outcomes of their internal testing, testing against the Provider Automated Test Suite, the Manual NHS Digital Test Scenarios and any Regression Testing. This may be done throughout development and/or at the end of development.  Refer to the document ‘GP Connect Test & Assurance Strategy for Providers for details on this. |
| Automated Testing (Connected to the Spine Server Proxy) | Provider / NHS Digital | The Provider will work with NHS Digital to connect a test version of their solution to the Spine Server Proxy (SSP). A re-run of the Automated Testing will take place and the results reviewed by NHS Digital. The purpose of this testing is to mimic a live NHS Spine environment and evidence that the solution can integrate with the NHS Spine |
| Witness Testing | NHS Digital & Provider | Witness testing will be undertaken for areas which are not covered by the automated test suite and/or through the weekly or bi-weekly test submissions or Teams sessions and are more appropriate to be assured through onsite witness test visits. |
| Data Mapping  FHIR Profile Population Spreadsheet | Provider | Provider completes a data model document confirming which data items can and cannot be provided. |
| Penetration Testing | Provider | The Provider is required to undertake a PEN Test for the release of each GP Connect API. If new architecture is introduced this will need to be PEN tested. Draft scope for PEN Testing should be submitted to NHS Digital for review and acceptance prior to test commissioning. Any modifications or recommended additions to the scope should be agreed between NHS Digital and the Provider.  Upon completion of any applicable testing, the Provider must submit a remediation plan to NHS Digital for review and acceptance. NHS Digital reserve the right to delay further roll out until such time as any significant defects identified be mitigated. |
| Ready for Operation Testing | Provider | Ready for Operations (RFO) testing by the Provider and assurance of the same by NHS Digital may be applicable if any new architecture is being introduced or  existing architecture is being significantly changed by the GP Connect API Provider to deliver the GP Connect API Service. |
| Non-Functional Testing | Provider | The Provider will be required to undertake Volume & Performance (V&P) testing to ensure that the volumetric model is achieved and that the underlying systems can deliver the volumetric model without impacting normal GP operations.  Ready for Operations (RFO) testing by the Provider and assurance of the same by NHS Digital may be applicable if any new architecture is being introduced or existing architecture is being significantly changed by the GP Connect API Provider to deliver the GP Connect API Service. |
| Deployment Verification Criteria | NHS Digital | An excel document will be produced outlining the minimum required Deployment Verification Criteria (which will be monitored during DVP):   * Service Performance – e.g. accuracy of reporting, performance issue areas, impact on existing networks and pre-existing technologies and data quality. * Business processes – impact on current and new processes from the implementation of the new product. * Incident Management – confirmation that there are no outstanding Severity 1 or 2’s and for any remaining defects to be recorded in an agreed work off plan |

**Milestones**:

An FoT Development Milestone Achievement Certificate (DevMAC) and Clinical Authority to Release (CATR) will be awarded by The Authority confirming all activities listed in above tables have been completed. This DevMAC will permit the Provider Supplier to move into the FoT Phase. After receiving the DevMAC and CATR, the Supplier will be required to submit an RFC to NHS DIGITAL Service Management to notify them that they intend to move from Design, Build and Test into Live Deployment.

## 4.3 First of Type (FOT)

**Overview**

In order to be awarded full compliance against the GP Connect API specification and data standards, a Provider solution must be deployed within a live environment and complete a First of Type (FoT) period with an assured GP Connect Consumer product (assured separately). This usually takes place within a small number of pilot sites.

After FoT entry has been granted at the end of the Design, Build and Test stage there needs to be a further round of integration testing with a Consumer solution prior to commencing with FoT. Test scripts for this testing will be provide by NHS Digital Solution Assurance who will oversee the testing process. The Provider must notify NHS Digital Change Management team of any sites that will be piloting this new solution and when they will be going live. A Request for Change (RFC) document will need to be submitted to NHS Digital by the Provider to facilitate this request.

Upon successful completion of integration testing, FoT will commence and there will be a period of monitoring. The DVC will be reviewed and exit criteria will have to be met as well as other factors that need to be considered before a FoT can be closed, for example, any work off items that the Provider has been asked to resolve prior to NHS Digital permitting FoT to close must be resolved.

After FoT closure, NHS Digital will again present evidence to CSG and Live Service Clinical Board including a FoT report and updated Clinical Safety Case and Hazard Log. If CSG and the Live Services Clinical Board agree that the FoT has met the desired success criteria and there are no outstanding work off items that must be fixed immediately, Full Rollout Approval (FRA) will be granted. The Provider must notify NHS Digital when they plan to release this solution to the rest of their estate.

The following deliverables are required and expected to be submitted during the FoT phase of the assurance process. Please note these deliverables

| Deliverable/Activity | Responsible | Approach |
| --- | --- | --- |
| Deployment Verification Criteria review | NHS Digital | The GP Connect enablement team will work alongside NHS Digital Service Management to review the DVC during FOT. NHS Digital Implementation & Business Change team will manage the FOT sites closely to ensure that the functionality is working correctly verifying against the DVC outlined above (DBT stage). This confirmation should be submitted to NHS Digital Service Management and the GP Connect Project Manager in order for FRA to be awarded. Any issues will be documented and raised with the supplier to resolve before FRA can be awarded, unless they are issues with little or no clinical impact. |
| Updated Safety Case & Hazard Log | Provider | The Supplier will update their Clinical Safety Case Report as and when required throughout FOT assurance. |
| FRA DevMAC | NHS Digital | An FRA will be granted by the Authority when all the Provider Activities and Deliverables and the Deployment Verification Criteria have been approved. |
| RFC | Provider | Supplier will submit an RFC for approval to progress to FRA. |
| Provider/Consumer Integration Testing (Spine Connected) | Provider (s) | Provider and Consumer products will be tested together within a Spine connected test environment.  Test scripts will be provided by NHS Digital Solution Assurance |
| FoT | Provider (s) | Provider and Consumer products will be tested together within the live environment.  This typically involves a small number of pilot sites using both Provider and Consumer systems together for an agreed period of time and with a target agreed acceptance criteria. |

**Milestones:**

The FOT DevMAC and Clinical Authority to Release CATR will be uplifted and an FRA (Full Rollout Approval) will be awarded by the Authority confirming all activities listed in above tables have been completed. This FRA will permit the Provider Supplier roll out more widely across their estate. After receiving the FRA and CATR, the Supplier will be required to submit an RFC to NHS Digital Service Management detailing their intended plans for further controlled rollout.

# Governance Processes

Where deliverables are received as documents, they will be circulated for appropriate stakeholder review with comments being returned within a five working days review window.  If required, calls will be arranged by the NHS Digital GP Connect project manager so that NHS Digital reviewers and the Provider can discuss and work through the comments.

Where a deliverable is to be submitted in the form of a workshop, the Provider will give ten days’ notice so that NHS Digital can ensure the availability of required stakeholders. A clear agenda and description of the content will be provided by the Provider. All materials/documents used in the workshop will be made available to NHS Digital in electronic format and, where practical, the workshop maybe be recorded.

# Virtual Team

This is the core GP Connect team for Access Record Structured who are actively involved in the project.

|  |  |  |
| --- | --- | --- |
| Role | Name | Contact Details |
| Project Manager | Simon Fitzgerald | Simon.fitzgerald4@nhs.net |
| Business Analyst | Martin Hillyard | martin.hillyard1@nhs.net |
| Technical Architect | Matt Stephens | matt.stephens1@nhs.net |
| Data Architect | Pete Salisbury | peter.salisbury@nhs.net |
| Functional - Solutions Assurance | Pete Gresty  Andrew Guiseley | peter.gresty@nhs.net  [andrew.guiseley@nhs.net](mailto:andrew.guiseley@nhs.net) |

The following people are key stakeholders:

|  |  |  |
| --- | --- | --- |
| Role | Name | Contact Details |
| Information Security | Peter Barrett | Peter.barrett1@nhs.net |
| Clinical Safety | Hannah McCann | zak.bickhan@nhs.net  Hannah.mccann4@nhs.net |
| Clinical Assurance | Dr Michelle Durham  Dr Neill Jones | Michelle.durham1@nhs.net  neill.jones@nhs.net |
| Service Management | Niti Patel | Niti.patel@nhs.net |

# Appendices

**Appendix A** – GP Connect Test Strategy for Providers



**Appendix B** – GP Connect Onboarding Consumer Assurance 



**Appendix C** – GP Connect IG Requirements - Compliance



**Appendix D** – FHIR Profile Mapping Template

