Technical Guidance

Patient Reported Outcome Measures (PROMs)

Published September 2017

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Contents

Glossary

Abbreviation	Definition
AES	Advanced Encryption Standard
Authenticated SEFT user key	The Supplier key exchanged with NHS Digital during registration for SEFT to permit authentication with NHS Digital SFTP Server.
FTP	File Transfer Protocol
Guidance	The guidance issued by NHS England which sets out and defines the requirements to which Suppliers and Providers are expected to adhere to in the delivery of PROMs services, the scope of PROMs in terms of eligible patients and the Questionnaire schemas to be used.
HES	Hospital Episode Statistics
Manifest	This is the file that accompanies the Payload file defining the submission file.
Payload File	This is the text file which is in the prescribed XML format
PROMs	Patient Reported Outcome Measures
Provider	Organisation responsible for providing NHS funded eligible procedures
Q1	Pre-Operative Questionnaire
Q2	Post-Operative Questionnaire
SEFT	NHS Digital's Secure Electronic File Transfer service
SFTP	Secure File Transfer Protocol
SSH	Secure Shell
Supplier	An organisation that is Accredited or seeking Accreditation, to support the collection, administration and reporting of PROMs data
Supplier Identifier	A unique identifier supplied by NHS Digital to each Supplier when registering for the SEFT service
PROMs Validation Report	XML report provided by NHS Digital detailing results of the validation process for the submitted file.
XSD	XML Schema Definition
XML	Extensible Markup Language

Background

This guidance should be read in conjunction with the National PROMs Programme Guidance document published by NHS England.

Healthcare Providers must collect PROMs data from eligible patients and will choose from a range of accredited survey contractors (Suppliers) potentially offering a range of survey administration solutions, from traditional 'paper and pen' data collection (minimum requirement) to electronic data capture solutions such as touch-screens or tablets.

Suppliers will submit collected PROMs data to NHS Digital, which is responsible for validity checking, scoring and weighting the questionnaire responses, linking individual questionnaire returns to the related patients' Hospital Episode Statistics (HES) records and/or their records held on other datasets and producing a range of derived data and indicators. NHS Digital then produces information and Official Statistics which can be used by the NHS, Providers, Commissioners and information intermediaries to drive improvements in the quality of NHS care. This information would normally be published in summary form as Official Statistics.
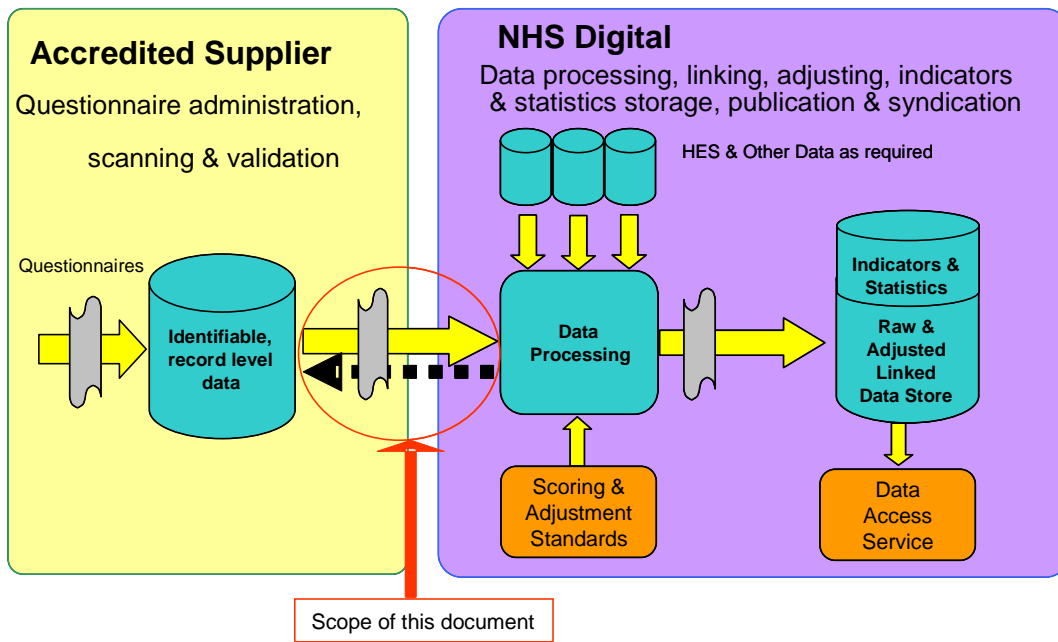
Purpose

This document sets out the technical requirements and processes necessary for organisations wishing to become PROMs Suppliers.

As part of the Accreditation process, potential Suppliers will be required to demonstrate that they can meet the requirements outlined in this document.

Once potential Suppliers have completed the Application phase, they will be required to undertake the Testing phase.

Following successful connection to NHS Digital's SEFT file transfer service and submission of a standard set of test data, organisations will become a PROMs Accredited Supplier.

Figure 1 below shows the relationship of this document to the wider context of the PROMS end to end process.

Accredited Supplier

Questionnaire administration, scanning & validation

Questionnaires

Identifiable, record level data

NHS Digital

Data processing, linking, adjusting, indicators & statistics storage, publication & syndication

HES & Other Data as required

Data Processing

Scoring & Adjustment Standards

Indicators & Statistics

Raw & Adjusted Linked Data Store

Data Access Service

Scope of this document

This document should be read in conjunction with the documents outlined in *Appendix 2*.

Pre-requisites for Connecting and Transferring Data to NHS Digital

Suppliers have a number of prerequisites to satisfy and maintain to be able to connect to the PROMs data interface and submit data to NHS Digital. They must:

1. satisfy and maintain the requirements of NHS England's National PROMs Programme Guidance

2. register to use NHS Digital's SEFT system for secure data transmission

3. have a File Transfer Protocol (FTP) Client supporting Secure File Transfer Protocol (SFTP) over Secure Shell (SSH)

4. have a NHS Organisation code

Compliance with NHS England's National PROMs Programme Guidance

In order to become Accredited to submit PROMs data to NHS Digital, Suppliers must demonstrate that they are able to meet the necessary requirements as set out in NHS England's National PROMs Programme Guidance before moving on to the Testing phase of the Accreditation process.

Suppliers will need to continue to adhere to the requirements of the guidance in order to maintain their Accreditation and continue to be able to connect to the PROMs data interface and submit data to NHS Digital.

SEFT System

All PROMs files MUST be submitted to NHS Digital securely via the SEFT system in the specified format as referenced in *Appendix 1* of this specification.

Suppliers will be required to register for the SEFT system via NHS Digital. Full details of the SEFT registration process and associated guidance will be provided upon request by NHS Digital.

FTP Client

Suppliers MUST have a FTP Client supporting SFTP over SSH using a public and private key pair for authentication.

NHS Organisation Code

Suppliers MUST have a NHS Organisation Code prior to submitting PROMs data to NHS Digital. NHS Organisation Codes will be allocated by Organisation Data Services within NHS Digital: https://digital.nhs.uk/organisation-data-service. A NHS Organisation Code can be requested by emailing: exeter.helpdesk@nhs.net

Security

The PROMs dataset contains Patient Identifiable Data (PID) and other sensitive information. As a result, all data MUST be treated in accordance with the Information Governance Toolkit.

All files MUST be submitted to NHS Digital via SEFT. This will ensure secure transfer using AES 256 bit encryption.

In addition to the secure encryption automatically provided by SEFT, Suppliers may also encrypt the submitted files if they wish. This MUST use WinZip 256 bit encryption and the Supplier MUST ensure that NHS Digital is notified of the password prior to submission.

Where encrypted files cannot be successfully decrypted, e.g. where the password within the file does not match the password held by NHS Digital, the submitted file will be rejected by NHS Digital.

Requisite Submission File Characteristics

Questionnaires will be collated by the Supplier into text files for submission. The format of the text file will be an XML document adhering to an XML Schema Definition (XSD) as referenced in *Appendix 1*. From this point forwards, the XML document will be referred to as the 'Payload file'.

An XML Manifest file MUST also accompany the file; the specification for this Manifest is referenced in *Appendix 1*. From this point forwards, the XML Manifest file will be referred to as the 'Manifest'.

- Each Payload file MUST contain questionnaires of one PROMs type and will contain only pre-operative (Q1) or post-operative (Q2) questionnaires.

- A Manifest file containing metadata describing the content and identifying the payload file must be included.

- The Payload file and Manifest together MUST be compressed in a zip file. Each zip file must contain 1 Payload file and 1 Manifest only.

System To System Interactions

All file transfers, in and out of NHS Digital, must be performed by connecting to NHS Digital SEFT system. Connections are made using SFTP over SSH.

Figure 2 shows the standard system to system interactions required to submit data to NHS Digital.
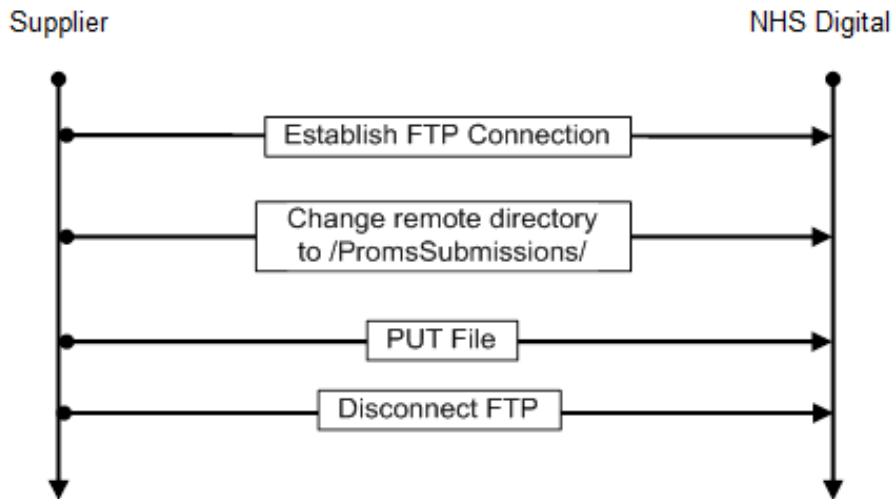
Figure 2 – File Submission

Figures 3 and 4 show the standard system to system interactions following submission of a zipped Payload file and Manifest to NHS Digital in order to deliver receipts and notifications to the Supplier.
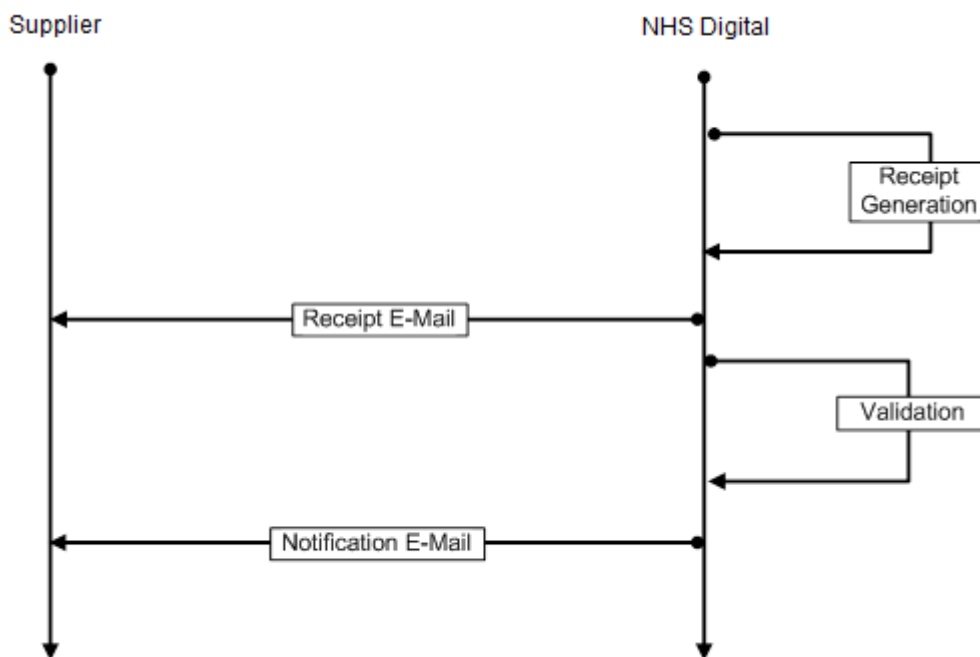

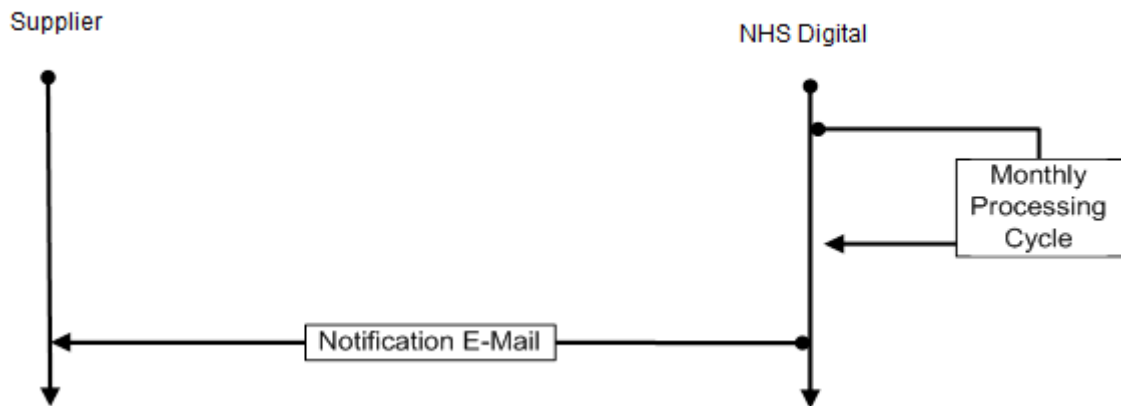Figure 3 – Receipt and Validation Notification E-Mails

Figure 4 – Post Processing Notification E-Mails

Figure 5 shows the system to system interactions required to collect PROMs Notifications. The FTP file path will be included in the e-mail notifications sent to the Suppliers which are shown in the above interactions.
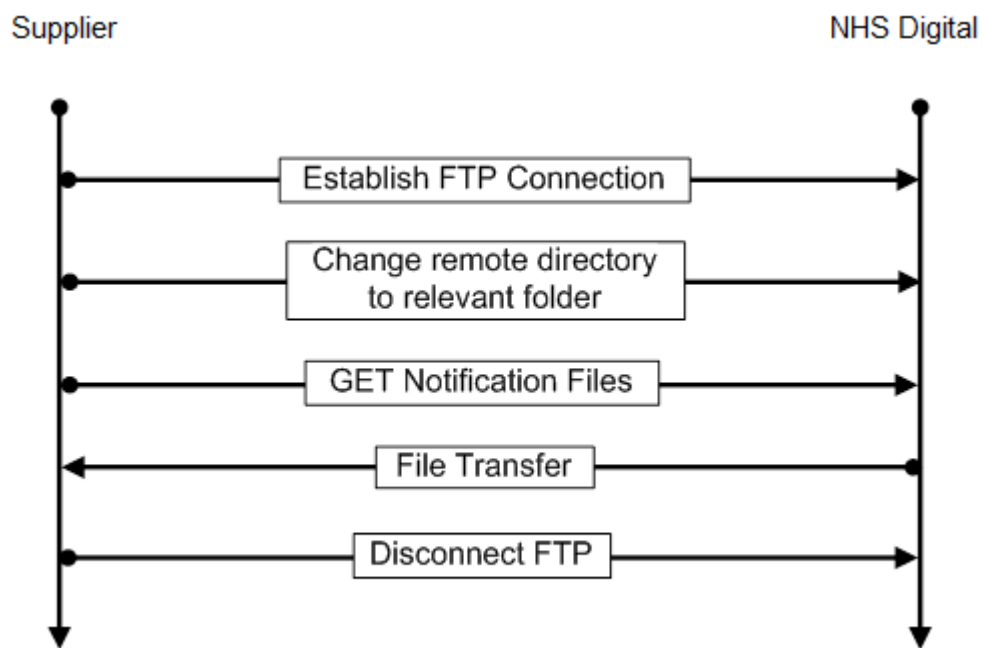

Figure 5 – File Retrieval

File Submission Process

Connecting

In order to upload or download files, a connection must be established using SFTP over SSH. Connection details will be provided upon registering for SEFT.

Authentication

During registration for SEFT, each Supplier will exchange keys with NHS Digital. The Supplier's FTP client should be configured to use the appropriate Authenticated SEFT user key to authenticate with NHS Digital SFTP Server.

Authorisation

Upon registration with NHS Digital, Suppliers will be issued with a Supplier Identifier. The Supplier Identifier must be included in the appropriate field in any Payload file or Manifest submitted to NHS Digital via this Data Interface. The Supplier Identifier must be used along with the Authenticated SEFT user key to ensure only authorised Suppliers are able to submit data, and to ensure a Supplier is unable to submit data with an incorrect Supplier Identifier.

Test Data Submission

Suppliers will be provided with a pack containing technical guidance and a standard set of test data in Comma Separated Value (CSV) format. These test files should be first converted to the required format as described in the pack's accompanying guidance before being submitted. Eight test files will be provided – pre and post-operative data for each of the four current procedures. To test validation routines, 7 of the files are designed to pass validation and one is designed to fail.

Once connected and authenticated with the NHS Digital FTP server, the Supplier will see a folder named 'PROMs Submission'. The zip file containing a Payload file and Manifest to be submitted should be dropped into this folder. The FTP protocol will provide feedback as to whether the transfer was successful. The submitted zip file will not be visible by the Supplier in the 'PROMs Submission' folder once submitted.

Upon successful receipt of the suppliers zip file by NHS Digital, NHS Digital will deliver to the supplier's nominated email account a notification of the receipt of the zip file.

A copy of the receipt will also be available for download from the following SEFT folder (see Figure 5).

Maximum File Size

Only files up to a maximum uncompressed file size of 150MB (approx 50,000 records) may be submitted within a single zip file. Where the file to be submitted exceeds this uncompressed file size, the file should be split and submitted as two separate zip files - each containing a manifest and payload file.

File Validation

All Payload files will be validated by NHS Digital upon receipt prior to further processing.

Any Payload file containing records that fail validation rules will be rejected and will not be processed further. All invalid records must be corrected or removed before the file is resubmitted.

Full details of Validation Rules will be published in the PROMS Validation Overview on NHS Digital website:

http://content.digital.nhs.uk/proms

Validation Reports

Details of all files and records failing validation will be contained within the PROMs Validation Report.

Users will be notified via email when the PROMs Validation Report is available to download from the following folder within the SEFT system:

/PromsNotifications/ValidationReports/

The Supplier will be required to connect and authenticate with the NHS Digital SFTP server to access their PROMs Validation Report.

PROMs Validation Reports will be available for download for two weeks from creation.

The XSD for the PROMs Validation Report is referenced in *Appendix 1*.

Change Management

This PROMs Technical Guidance and the XML Schemas detailed in Appendix 1, are subject to change in order for improvements to be made.

Accreditation Notification

An official email will be issued to the Supplier upon evidence that all accreditation requirements have been met. A copy of this email will also be provided to NHS England.

This will include details of all PROM XML schemas which the Supplier is accredited to submit. An updated Accreditation notification will be issued upon any change to Supplier Accreditation details.

This will be issued following the annual completion of the IGT as a minimum, but also following the issuing of any new PROMs questionnaires or successful submission of new or updated PROMs XML schemas.

PROMs Accreditation Details

Details of PROMs Supplier Accreditation including the Accreditation status of each Supplier will be maintained by NHS Digital.

Maintaining Accreditation

Suppliers must maintain the requirements of Accreditation to be able to connect to the PROMs data interface and submit data to NHS Digital. This will include completion of the IGT on an annual basis to a specified minimum attainment level and the successful submission of files compliant with existing, revised or new XML schemas specifications.

Suppliers are required to notify NHS Digital if they no longer satisfy the requirements for Accreditation.

Suspension and Reinstatement of Accreditation

Suspension of Accreditation

In exceptional circumstances Supplier Accreditation may be temporarily suspended.

NHS Digital will issue notification of the temporary suspension of Accreditation of the Supplier to NHS England outlining the required remedial actions and associated timescales.

Where Accreditation has been suspended, the Supplier will be prohibited from submitting 'live' PROMs data to NHS Digital. Any 'live' submissions of PROMs data during the period of suspension will be rejected by NHS Digital. This would normally affect Supplier payment.

Scenarios that may lead to the suspension of Accreditation include:

- Information Governance requirements no longer being met

- Inability to successfully submit data in the correct format

Reinstatement

Accreditation will be reinstated upon the Supplier providing evidence to NHS Digital that the remedial actions have been undertaken within the prescribed timescales. Suppliers will be able to resume 'live' submission of PROMs data to NHS Digital following the reinstatement of Accreditation.

Revocation of Accreditation

NHS England retains the right to revoke the accreditation for the Supplier if the Supplier is in breach of the Accreditation requirements, with Accreditation not to be unreasonably withdrawn.

Roles and Responsibilities

NHS England

NHS England will:

- notify NHS Digital of any additions or changes to the records of Accredited Suppliers within 24 hours
- revoke Accreditation for a Supplier should it consider the Supplier to be in breach of the National PROMs Programme Guidance requirements

NHS Digital

NHS Digital will:

- provide details and guidance to support the Accreditation process for Suppliers
- provide test data files to Suppliers
- provide XML schema specifications and associated guidance to Suppliers
- confirm Supplier is compliant with licensing arrangements,
- confirm Supplier has satisfactory IGT attainment Level 2
- confirm Supplier has successfully transferred files in the specified format
- confirm Supplier has successfully submitted data in the specified format
- issue the accreditation notification to Suppliers
- issue a Warning to a Supplier
- suspend the Accreditation
- maintain the service management of NHS Digital function for the duration of the framework agreement

Supplier

The Supplier will:

- initiate the SEFT registration process by contacting NHS Digital
- initiate the Accreditation process by contacting NHS Digital
- provide a statement of compliance (and where appropriate, evidence of compliance) with licensing requirements to NHS Digital
- complete the IGT on an annual basis
- provide details of the PROMs IGT attainment level to NHS Digital

- confirm that they can successfully receive and are able to use the validation report to resolve any issues prior to resubmission
- resolve all issues identified during test submission and resubmit corrected files within 24 hours

Accreditation Process

Any Supplier wishing to commence Accreditation should contact NHS Digital for full details.

Telephone: 0300 303 5678
Email: enquiries@nhsdigital.nhs.uk (please include 'FAO PROMs' in subject line)

Suppliers who have not already done so will be required to register for the SEFT system. Full details of the SEFT registration process and associated guidance will also be provided upon request by NHS Digital.

Further Information and Support

For enquiries relating to the PROMs including scope, data items, definitions and data values, PROMs XSDs, submission requirements, Supplier accreditation and SEFT registration please contact NHS Digital:

Telephone: 0300 303 5678
Email: enquiries@nhsdigital.nhs.uk (please include 'FAO PROMs' in the subject line)

Appendix 1 – XML Schema Definitions

The latest version of the PROMS XSD schemas supported by NHS Digital will be available from NHS Digital in the following document:

'PROMs_DataSpecification_v0.13.xls

A WinZip file containing the PROMS XSD schemas and sample XML files will also be provided upon request from The NHS Digital Contact Centre:

enquiries@nhsdigital.nhs.uk (please include 'FAO PROMs' in the subject line)

Appendix 2 – Supporting Documents

This document should be read in conjunction with the following documents:

- PROMs Supplier Accreditation Process

- National Patient Reported Outcome Measures (PROMs) Programme Guidance

- Patient Reported Outcome Measures (PROMs) in England - A guide to PROMs methodology

- PROMs Accredited Supplier Application Form