Professional
Record
Standards
Body

CONFORMANCE ASSESSMENT METHODOLOGY

Excellence in conformance with health and social care information standards

PRSB PARTNER

PRSB QUALITY PARTNER

INTRODUCTION

The PRSB Standards Partnership Scheme connects health and social care digital system suppliers with the PRSB, to accelerate the implementation of PRSB standards. The scheme is supported by system leaders in the NHS and social care. Achieving our PRSB Quality Mark for standards conformance provides independent evidence of best practice to your customers, system leaders, commissioners and regulators.

The Quality Mark is awarded based on successful conformance, which is explained later in this document. Gaining the Quality Mark gives a clear and independent view of conformance to those purchasing software systems.

Our approach is collaborative and developmental. We aim to encourage progress on the journey to full conformance. We work as 'partners' with you, using the process to also learn and improve the standards, ensuring they are usable.

This document describes the methodology used to assess conformance with standards and the criteria used to award the Quality Mark.

PRSB QUALITY PARTNER

PSRB STANDARDS

PRSB work with service users, professionals and system suppliers to define the standards needed for good care records. We are a unique collaboration of groups representing those who receive and provide health and social care across the UK, as well as those providing the IT systems that support care.

PRSB standards incorporate an Information Model. This is a list of sections or groups of headings with data items. There is a set of rules governing their development and implementation in systems, and their use by system users. Each data item has an associated description, conformance category, cardinality and value set, which must be adhered to for 100% compliance.

It is strongly advised to implement the standard in accordance with the implementation guidance and clinical safety case documentation, which can be found on our standards pages.

Find out more about PRSB standards and how they are developed

Name	Conf [-]	Card [-]	Description [-]	Context [-]	Operationalizations [-]
▼ Allergies and adverse reactions	R	0 ... 1	Allergies and adverse reactions		
▼ Allergies and adverse reactions record entry	R	0 ... *	This is a allergies and adverse reactions record entry. There may be 1 to many record entries under a section. Each record entry is made up of a number of elements or data items.		
Type of reaction	R	0 ... 1	The type of reaction experienced by the person (allergic, adverse, intolerance)		FHIR value set :- Allergy, Intolerance
Causative agent	M	1 ... 1	The agent such as food, drug or substances that has caused or may cause an allergy, intolerance or adverse reaction in this person Or "No known drug allergies or adverse reactions" Or "Information not available"		
▼ Reaction details cluster	R	0 ... 1	Details of the reaction.		
Date	R	0 ... 1	The date that the reaction was identified.		Date and time
Location	R	0 ... 1	Details of where the allergy was identified. Linked to the date of the diagnosis by the professional.		
Substance	R	0 ... 1	The substance, or a class of substances, that is considered to be responsible for the adverse reaction.		
Description of reaction	R	0 ... 1	A description of the manifestation of the allergic or adverse reaction experienced by the person. For example, skin rash.		
Severity	R	0 ... 1	A description of the severity of the reaction.		
Certainty	R	0 ... 1	A description of the certainty that the stated causative agent caused the allergic or adverse reaction.		
Comment	R	0 ... 1	Any additional comment or clarification about the adverse reaction.		Free text
Evidence	R	0 ... 1	Results of investigations that confirmed the certainty of the diagnosis. Examples might include results of skin prick allergy tests		Free text
Date first experienced	R	0 ... 1	When the reaction was first experienced i.e this may not be the first this has happened. May be a date or partial date (e.g. year) or text (**e.g. during childhood**)		Date and time
▼ Performing professional	R	0 ... 1	The professional who identified the reaction.		
Name	R	0 ... 1	The name of the professional.		Free text.
Role	R	0 ... 1	The role the professional has in relation to the person e.g. GP, physiotherapist, community nurse, social worker etc		FHIR value set :- SDSjobroletype
Grade	R	0 ... 1	The grade of the professional.		Free text
Speciality	R	0 ... 1	The specialty of the professional e.g. physiotherapy, oncology, mental health etc		NHS data dictionary - Activity treatment function code
Professional identifier	R	0 ... 1	Professional identifier for the professional e.g. GMC number, HCPC number etc or the personal identifier used by the local organisation.		NHS data dictionary : - Professional registration identifier
Organisation	R	0 ... 1	The name of the organisation the professional works for.		
Contact details	R	0 ... 1	Contact details of the professional		NHS data dictionary - UK phone number
▼ Person completing record	R	0 ... 1	Details of the person completing the record.		
Name	R	0 ... 1	The name of the person completing the record.		Free text.
Role	R	0 ... 1	The organisational role of the person completing record.		FHIR value set :- SDSjobrole
Grade	R	0 ... 1	The grade of the person completing the record.		Free text.
Specialty	R	0 ... 1	The main specialty of the person completing the record.		NHS data dictionary :- Activity treatment function code
Organisation	R	0 ... 1	The organisation the person completing the record works for.		NHS data dictionary : - Organisation data service
Professional identifier	R	0 ... 1	Professional identifier for the person completing the record e.g. GMC number, HCPC number etc, or the personal identifier used by the local organisation.		NHS data dictionary :- Professional registration identifier
Date completed	R	0 ... 1	The date and time the record was completed.		Date and time.
Contact details	R	0 ... 1	Contact details of the person completing the record.		NHS data dictionary : - UK telephone number

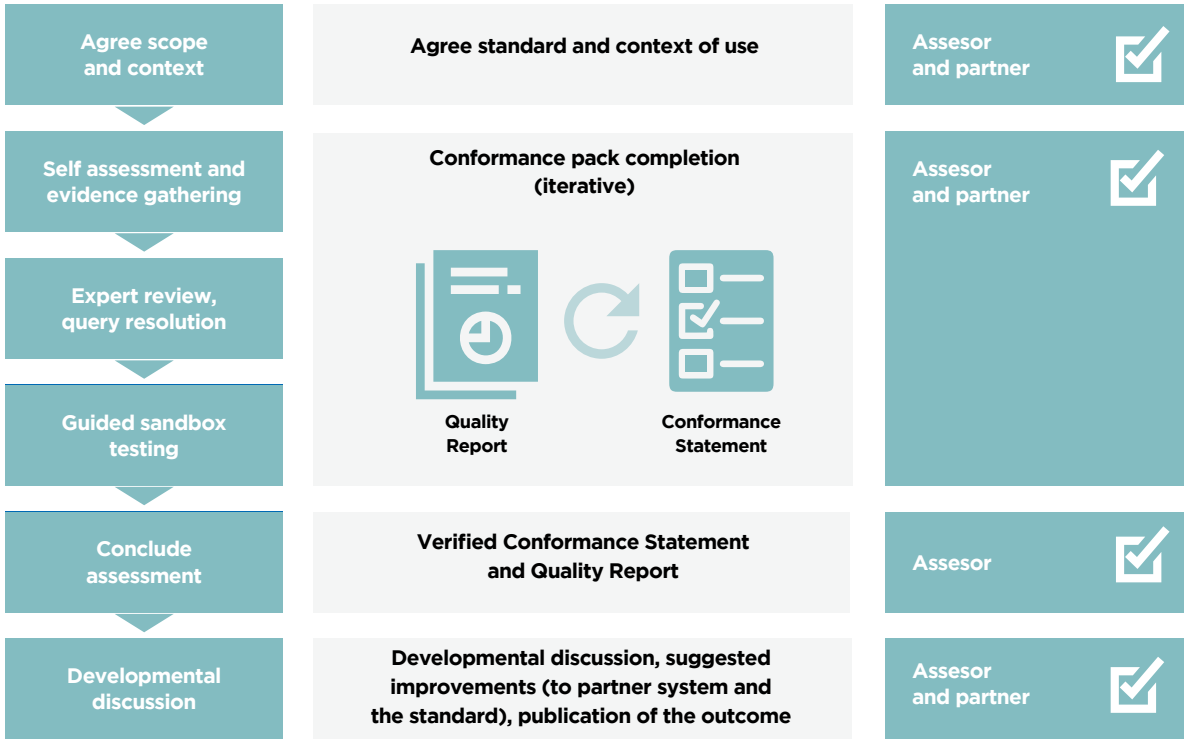
THE CONFORMANCE ASSESSMENT PROCESS

Each PRSB standard has an accompanying conformance pack. This includes the self-assessment spreadsheet that contains the information model and business rules for a standard. Email partners@theprsb.org for copies of the conformance packs. To commence the process, one of our expert assessors will meet with you to discuss how conformance against the relevant standard or standards is assessed. You will then complete the self-assessment form and meet with the assessor again to validate the contents of the form. Our assessors are on hand to provide you with guidance throughout the process.

Two expert assessors will work together with you to review the contents of your self-assessment form, and then run test cases through your system to provide direct evidence. The results are reviewed by an internal panel and the outcomes agreed, including validating the Conformance Report and the contents of the Quality Report.

By participating in an assessment, you can engage in dialogue and challenge about specific areas of standards that are missing, not used or require amendment. PRSB recognises the value of this process in driving uptake and adherence to standards in health and care systems and ensuring standards work effectively.

The outputs of the assessment process are a validated Conformance Report and a Quality Report and Quality Mark. The contents of the Quality Report remain confidential to you.



WHAT IS ASSESSED?

The PRSB assesses:

- Information model –
  Data item with its associated:
  - Conformance
  - Cardinality
  - Value set
- Business rules and requirements
- Organisational best practice

To be considered conformant, a system should have at least 40% of data items correctly implemented, and all the 'must have' data items and business rules for a standard, and the 'must have' organisational assurance criteria. The table above is an extract from one of our standard conformance packs and indicates examples of must have items.

PRSB recognises that our partners might be at the start of their journey to data conformance and organisational best practice in standards and few, if any, will be 100% compliant from the start.

The assessment is intended to recognise and encourage positive, incremental progress in adopting standards. Therefore, we award levels of conformance with the ultimate aim of achieving 100% implementation of the standard.

Section	Type	Name	Conformance	Cardinality	Value Sets	Must Haves
Person demographics	**Section**	**Person demographics**	**M**	**1...1**		**Must Have**
Person demographics	Group	Person name	M	1...1		Must Have
Person demographics	Item	Person first name	M	1...1	NHS data dictionary :- Person given name	Must Have
Person demographics	Item	Person family name	M	1...1	NHS data dictionary : - Person family name	Must Have
Person demographics	Item	Person preferred name	R	0...1	NHS data dictionary: - Person full name	
Person demographics	Item	Title	R	0...1	NHS data dictionary: - Person title	
Person demographics	Item	Person name suffix	R	0...1	NHS data dictionary: - Person suffix	
Person demographics	Item	Person full name	R	0...1	NHS data dictionary :- Patient full name	
Person demographics	Item	Date of birth	M	1...1	NHS data dictionary:- Person birth date	Must Have
Person demographics	Item	Gender	R	0...1	NHS data dictionary :- Person stated gender	
Person demographics	Item	Person alias	R	0...*	Free text	
Person demographics	Item	Ethnicity	R	0...1	NHS data dictionary :- Ethnic category	
Person demographics	Item	Religion	R	0...1	SNOMED_CT:- Religion	
Person demographics	Item	Sex	R	0...1	NHS data dictionary: - person phenotypic sex	
Person demographics	Item	NHS number	R	0...1	NHS data dictionary:- NHS number	Must Have

Level 1 conformance

40-49%

This shows a system has all the 'must have' data items and business rules and a **moderate** proportion of the required data items.

Level 2 conformance

50-69%

This shows a system has all the 'must have' data items and business rules and a **significant** proportion of the required data items.

Level 3 conformance

70-100%

This shows a system has all the 'must have' data items, business rules and the **majority** of the required data items.

100% of data items is the gold standard.

All the 'must have' data items in the right cardinality and value set.
All the 'must have' implementation requirements.
All the 'must have' organisational assurance criteria met.

WHAT IS THE QUALITY MARK?

The Quality Mark is awarded to a specific version of a software system. It indicates that you have achieved the minimum threshold of conformance for a safe and effective instance of a defined version of a standard in your system. It also shows that you have demonstrated a strategic commitment to leadership in standards.

Partners who attain the Quality Mark are recognised on our website with details of the system assessed, standard(s) tested, level of conformance reached and dates of the assessment. The Quality Mark may be applied to the materials and communications you develop about your conformant system.

Digital applications of the Quality Mark must be hyperlinked to the PRSB website, providing visitors with the means to discover the purpose of the logo and the listing of conformance details. See the Terms & Conditions of the Standards Partnership Scheme for more details.

Use of the Quality Mark does not infer any judgement on the quality, safety or use of a partner's system. The Quality Mark represents an assessment of how a standard has been implemented using the PRSB's assessment criteria. It does not infer any judgement on the quality, safety, utility or appropriateness of your information system or application.

HOW DOES THE QUALITY MARK REMAIN CURRENT?

The Quality Mark is awarded to a system for three years. The Quality Mark will be withdrawn if a partner decides not to undergo re-assessment at the three-year mark.

In exceptional circumstances, where safety is a significant risk, PRSB will release an emergency update of a standard. In this case, PRSB reserves the right to request reassessment of a system against the new release to maintain the validity of the Quality Mark.

WHAT IS THE GOVERNANCE AND ASSURANCE PROCESS?

The scheme is overseen by an Operational Board which meets quarterly. Every Quality Report and Verified Conformance Statement is reviewed and signed off by the PRSB Assurance Committee.

Our conformance methodology has been reviewed and tested widely by clinical, professional and informatics experts and our Advisory Board membership and will be kept under continuous review.

FAQS

What does an assessment focus on?
An assessment focuses on a specific system (and version) and the organisational practices associated with delivering that system. If a system is awarded the Quality Mark, this does not mean other similar systems (or versions of the system) can claim the Quality Mark. They would need to be assessed separately.

What happens if a system fails the assessment process?
You will still be acknowledged as a partner and will receive all the benefits of partnership. The fact that you have not been successful in the assessment process will be kept confidential by PRSB. You will be free to request reassessment (at additional cost) at any time you wish.

How does PRSB ensure the assessment process is fair and consistent?
The assessment uses a set of validated instruments (conformance packs) and a robust methodology that is applied consistently across assessments, regardless of the standard or type and size of partner.

How does PRSB assure independence?
PRSB health and care experts involved in assessment are fully trained and adhere to PRSB guidelines. Our assurance process ensures all decisions and outputs are objective and endorsed. A separate team of health and care experts conduct assessments, and these are validated by our Assurance Committee.

Does the Quality Mark mean a system supports interoperability?
The Quality Mark indicates a system has attained an acceptable level of conformance with the Information Model, i.e. data items for a standard. These data items form the building blocks for exchanging structured data across systems.

Does the Quality Mark say anything about the usability of a system?
The business rules associated with a standard include some functionality related to usability; for example, rules about how information should be displayed or navigated. However, the Quality Mark does not infer usability of a system.

Does the Quality Mark infer a system is clinically safe?
Clinical safety is the absence of preventable harm to a patient during the process of health and care and reduction of risk of unnecessary harm associated with health and care to an acceptable minimum. While conformance to a standard plays a role in this, the Quality Mark does not infer a system is clinically safe.

Does the Quality Mark mean a local implementation of a system will be conformant with one or more standards?
If your system has the Quality Mark, it is conformant with one or more standards in the configuration supplied by you. However, a local provider may choose to customise a system in a way which is not conformant. Local assessment will be required to demonstrate conformance of the local customisation of the system.

Once the Quality Mark has been awarded, how does PRSB ensure its ongoing validity?
The Quality Mark is valid for three years from the award date, with an annual check-in with assessors. To retain the Quality Mark, partners are expected to undertake reassessment.

CONTACT US

If you are interested in joining the Standards Partnership Scheme, contact us via the website or talk to a member of our team:

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020 4551 5225
theprsb.org/partnerscheme

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