GS1 Australia

The Global Language of Business

# GS1 Healthcare

## The 10-step guide for healthcare providers to implement GS1 standards

# Contents

# Why GS1 standards for healthcare providers?

Healthcare providers seek to ensure high quality care for their patients. Doing so is also an expectation of professional standards of practice. However, complex clinical and business processes, time constraints, and multiple demands often pose challenges that may inadvertently contribute to risk. This means healthcare providers are becoming more and more aware that implementation of GS1 standards, as a foundational part of clinical or business processes, provide a range of organisational benefits. GS1 standards help to improve patient safety, allow caregivers more time with patients and drive business efficiency, effectiveness and cost reduction.

GS1 standards are being used by an increasing number of suppliers, both for medicinal products and medical devices, meaning healthcare providers can now take the opportunity to review their processes and IT systems to see how and where the use of these global standards provide benefit.

The fundamental step of scanning a globally unique identifier in a globally standardised barcode, will help to enable automation of processes, such as recording products used at the point of care, receipt of goods in all areas within the hospital, inventory control, medicinal product dispensing and administration controls, capturing product data in registries and improving accuracy of patient records.

In addition, there is now clear awareness that using localised proprietary approaches introduces the risk of error, adds cost, eliminates the possibility of visibility and traceability, and creates overall inefficiency.

Given that healthcare is a global sector, with products crossing borders and patients moving between facilities, GS1 standards have an important role to play to improve the patient journey.

Simply put, there is a need to ensure what is held and referred to in one department or healthcare provider facility can be acknowledged and shared with others irrespective of physical or technical boundaries.

This guide aims to assist healthcare providers with the GS1 standards implementation process, to ensure implementation is undertaken correctly and all anticipated benefits are realised.

## Purpose of this guide

This document is designed as a simple step by step guide for healthcare providers starting to implement GS1 standards.

The document is not specific to a particular healthcare provider, clinical or business process, nor to an element of the GS1 standards, but rather provides the considerations, recommendations and guidance needed to move forward with whichever process and standards' combination is chosen.

# Who should use this document?

Representatives from departments of healthcare providers who wish to start implementing GS1 standards should refer to this document.  Often the steps in this document will be undertaken in conjunction with support and guidance from the local GS1 Member Organisation.

# Prerequisites

The reader must have an understanding of the details of the GS1 standards or a mechanism to gain that knowledge for their organisation (either directly or via support from their local GS1 Member Organisation).

# GS1 Healthcare and GS1 standards

GS1 Healthcare is a global, voluntary user community bringing together all healthcare supply chain stakeholders; manufacturers, distributors, healthcare providers, solution providers, regulatory bodies and industry associations. GS1 Healthcare members include over 70 leading healthcare organisations worldwide.

GS1 standards are used by healthcare organisations of all sizes, representing all parts of the supply chain, to help improve patient safety and enable supply chain accuracy and efficiency.  These standards are:

**1.** Global – GS1 standards ensure globally unique identification and enable cross-border compatibility of identification.

**2.** Robust – Today, in various sectors, over 6 billion transactions per day are enabled by GS1 standards, demonstrating robustness.

**3.** Multi-sector –  Using the same standard to identify and trace healthcare and non-healthcare items ensures compatibility for healthcare stakeholders sourcing a wide variety of items.

**4.** User-generated – GS1 standards are built and maintained collaboratively by volunteers from across the world representing every part of the supply chain.

**5.** Scalable – GS1 standards meet the needs of a small rural hospital as well as a multi-national supplier.



# Acknowledgements

# 10 High-level steps to implementation of GS1 standards by healthcare providers

To ensure successful implementation of GS1 standards in clinical or business processes, the following high level implementation steps are recommended:

**1.** Select the clinical or business process where GS1 standards provide benefit

**2.** Analyse the current and future desired situation, then build the business case

**3.** Establish a working structure

**4.** Use a project methodology

**5.** Develop technical solutions and undertake as-is state measures

**6.** Execute training and create documentation

**7.** Complete first stage implementation

**8.** Deploy new standards-based processes

**9.** Evaluate

**10.** Monitor, refine and expand

## Step 1: Select the clinical or business process where GS1 standards provide benefit

It is important to gather as much information as possible to understand options and opportunities for implementation of GS1 standards within an organisation's clinical or business processes. Simply put, this information is needed to define the business and/or clinical process you want to refine. The more information sourced, the more effective the implementation will be.

### Learn from others

The best way to gather information is to learn from others who have successfully implemented GS1 standards. This will help with understanding what is possible as well as implementation approaches.

### Identify where to start

It is possible there are multiple business or clinical processes for which GS1 standards implementation will provide benefit. A high level assessment should be made to select the priority areas. This could be done using the following criteria:

- Organisational value from implementation
- Capability to implement
- Drive to implement
- Cost of Implementation
- Time / ease of implementation
- Change management requirements
- Overall business benefit

This will enable an organisation to reach a factually based decision about the best clinical or business process to use to start the implementation of GS1 standards.

For information about the range of processes in which GS1 standards provide benefit, refer to the GS1 Healthcare Business Process Matrix, available from your local GS1 Member Organisation (http://www.gs1.org/contact).

### Outcome

The key stakeholders within the organisation will have an understanding about the possibilities for implementation of GS1 standards in clinical and business processes, opportunities will have been assessed and a starting point selected.

Refer to:

- GS1 Healthcare Reference Books – these annual publications contain case studies of GS1 standards implementations by healthcare providers http://www.gs1.org/healthcare/reference-books)

- GS1 Healthcare conference presentations – the first day of the GS1 healthcare conferences focusses on healthcare provider implementation and these presentations / videos are excellent references (http://www.gs1.org/healthcare/events)

- GS1 Healthcare Channel on You Tube – here you will find case study videos showing various GS1 standards implementations by healthcare providers (https://www.youtube.com/user/GS1Healthcare/featured)

- Healthcare Provide Advisor Council (HPAC) monthly webinars which focus on case study implementations of GS1 standards (http://www.gs1.org/healthcare/hpac)

- Independent research that quantify the benefits of standards adoption, such as the McKinsey report Strength in unity: The promise of global standards in healthcare (http://www.gs1.org/healthcare/mckinsey)

- Government reports that provide the business case for GS1 standards adoption, such as the UK NHS eProcurement strategy (https://www.gov.uk/government/publications/nhs-e-procurement-strategy) and the UK Carter Report (https://www.gov.uk/government/news/review-shows-how-nhs-hospitals-can-save-money-and-improve-care)

- Your local GS1 Member Organisation, who can provide access to local case studies and support resources (http://www.gs1.org/contact)

- GS1 website: www.gs1.org/healthcare

## Step 2: Analyse the current and future desired situation, then build the business case

It is important to understand the current situation in order to prioritise the clinical or business process, including successes and issues, as well as to have a clear vision of the desired situation. During this step it is important to assess the current state, scope the desired future state and identify the gap between the two.

### Assess the current situation (as-is state)

To gain a detailed understanding the as-is state two study approaches should be considered:

1. Follow the process today using an example. Undertake a step by step study of what happens, what works and barriers or issues. Understand the information that need to be gathered at each step, where that information is sourced (e.g., data entry, hand written records, etc) and where the information is stored and/or shared between individuals and/or systems.

2. Interview key stakeholders involved in the process of today as their anecdotal feedback will be extremely valuable as input to the overall process redesign. If the implementation will involve participation of trading partners or solution providers, it is important at this stage to assess their readiness to partner in a new implementation.

If the business or clinical process in question involves external stakeholders (i.e., either external to the department or to the organisation, such as a solution provider), ensure they are consulted during this step.

## Scope the desired situation (to-be state)

Using the information gathered in the as-is state assessment, document the to-be state. The documentation will provide a vision of the value and importance of the future stage, and explain the high-level steps, work/processes, needed to close the gap between current state and future state. The documentation will identify:

1. At which process points GS1 standards will apply

2. Necessary process step or system changes, e.g., data capture methods and data formats, external data sources, process step amendments, responsibility reassignment, etc.

3. If current IT system software capabilities meet the needs of the changed process (e.g., data field lengths and structures), and if the IT systems are linked in an appropriate way

4. Hardware capability gaps, e.g. lack of barcode scanners or label printers

**Remember:**

• Make sure the to-be state is tested with the external stakeholders engaged in the initial as-is state review. It is important to refine and update the to-be process based on feedback received. This will ensure that there are no issues during roll out of the process.

• Focus on the clinical or business functionality desired, not the technical capabilities. Technical solutions are driven by the clinical and business needs, not the reverse. However, it is important that the technical solutions fit the clinical and business needs. It is important to understand if an IT system or IT hardware upgrade or replacement is needed, an important factor to include in the business case.





## Build the business case

Based on this thorough analysis, a high-level business case will be created which will detail areas including:

• Overall process and timelines for implementation

• Clearly articulated desired situation

• Stakeholders

• Senior sponsor

• Expected return on investment. To assist with building the business case your organisation could reference the experiences of others, but also the implementation cost and savings calculators developed by some GS1 Member Organisations, for example, the calculator from GS1 Australia can be accessed at https://savingscalculator.gs1au.org/Login.aspx

• Implementation reference sites

• Resource requirements

• Expectations of external stakeholders such as solution providers and suppliers

• IT system or hardware requirements, e.g., system modifications or hardware / software purchases

• Budget requirements

The business case will be used for Senior Management or Board level assessment of the proposed project and ultimately the go / no go decision.

## Outcome

The as-is state is understood, the to-be state agreed and documented, and a comprehensive business case developed to allow for Senior Management / Board decision making about whether to proceed.

## Step 3: Establish a working structure

Once the decision to proceed has been made, the project process should be formally initiated and stakeholders should be identified. A foundational part of this is to clearly communicate tasks and responsibilities.

### Form the project team

A project manager will be appointed and the project team formed. Based on the business case and desired to-be state, the involvement of the Senior Management sponsor will be essential to ensure that a correct mix of resources is committed to the project from the relevant internal departments. The project manager will lead the assignment of internal tasks and responsibilities, and seek feedback from the project team members. It is important the project team members understand the overall goal, expected organisational benefits, and are absolutely committed to the project.

Keep in mind the project team may include participants such as trading partners, who are external to your organisation. Alternatively the team may choose to put in place a structure where those not involved directly, but who need to be kept abreast of developments, receive regular status updates.

### Ensure GS1 standards knowledge

Your organisation may appoint a person responsible for GS1 standards knowledge, in which case this person will need to ensure they have the latest information. Contact your local GS1 Member Organisation to help you navigate through and understand the GS1 standards, for education and training, alignment of needs with current or future standards, and/or engagement in respective local and/or global working groups where you can engage with peers and contribute to the standards development process within the healthcare sector. In addition, local GS1 Member Organisation can facilitate best practice discussions based on other successful projects.

Alternatively the local GS1 Member Organisation could be an important addition to the project team to ensure accurate advice and guidance regarding implementation of the standards. It is important that the GS1 Member Organisation is the knowledge bank and the project team is the driving force in the implementation process.

### Outcome

An enthusiastic and committed project team will be functional only if all participants understand the overall aim of the project. Responsibility for ensuring accuracy of GS1 standards information will have been assigned.
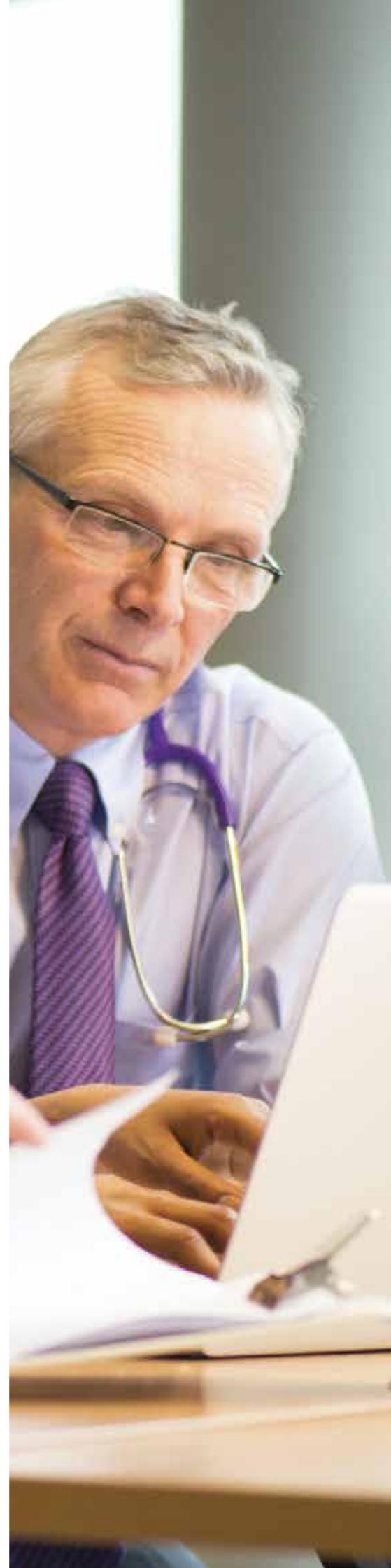
# The project has officially started!

## Step 4: Use a project methodology

Now the project team has been assembled, the project officially commenced. The next step is to further implement the project methodology. During this step, important project decisions will be made. These provide the foundation for the implementation tasks that follow.

### Define the scope and timeline

Based on the business case, the first role of the project team is to agree on the final implementation scope. The scope will clearly detail the boundaries of the project and as a result identify if external parties need to be engaged to participate. The next task is to develop a detailed project timeline aligning with that stated in the business case. It is important to have in place contingency for delays or inability of all stakeholders to participate in line with the project deadlines. For example, if the goal is to involve 3 trading partners in the first implementation, select 5-6 to participate on the basis that some may be unable to participate within timelines based on their own internal capabilities.

To define the scope and timeline, a number of questions need to be answered, including:

- What are the ultimate objectives and results?

- What is inside and outside scope?

- What are the constraints?

- Who are the stakeholders who need to be engaged outside of the project team?

- What is the relationship with other projects?

- What is the final budget?

- What activities are undertaken?

- What baseline measures should be captured prior to implementation (in the as-is state) and post-implementation (in the to-be state)?

### Define what success looks like and specific measures

At this stage, a plan that includes immediate, mid- and long-term goals and tasks should be identified.  Supporting this, define key metrics to enable consistent measurement of value and impact. Metrics are important, not only to assess the success of the project but also overall impact on clinical and business processes.  When measured in both step 5 and step 9, these can be structured to be reported to relevant stakeholders including Senior Executives and Board. Metrics may be both qualitative as well as quantitative and need to reflect perspectives of stakeholders engaged with the implementation from its conception through to service delivery. Metrics collected will also help to positively reinforce the commitment and time from staff to implement the GS1 standards.

## Develop functional specifications

The relevant stakeholders in the project team will need to develop and agree on detailed functional specifications for the new process. Additionally, it is important to consider if this project may align with other internal projects.

## Identify if external IT partners need to be engaged

Based on the documented to-be state and the functional specifications, any gaps in the current IT capabilities, both software and hardware, will have been identified. The project team then has the responsibility to determine if these gaps are able to be addressed using internal skills or if external partners need to be engaged.

If the decision is made to engage external partners, the following needs to be considered:

- Is there an existing partner that can provide the needed support within the allocated budget, e.g., the current software supplier or scanner supplier?

- Does a tender need to be run to select the appropriate external partner?

- What is the strategy to support the transition from legacy data to standards adoption and/or alignment with other data sources?

Either way, it is extremely important to ensure an accurate high-level briefing is given to these external partners and they are advised correctly regarding the GS1 standards. It is recommended any documents issued relating to required GS1 standards capabilities be validated with your local GS1 Member Organisation. GS1 Member Organisation resource can also be involved in the functionality discussions with system providers or make necessary connections at other hospital providers but cannot be involved in pricing discussions. The same validation should be done with any responses to tender made by solution providers to ensure accuracy and completeness.

To ensure transparent accountability when the implementation transitions to business as usual, it is important that the project team member agreeing the contract with an external IT partner knows and can communicate in detail to the remainder of the project team exactly what tasks the Solution Provider is to fulfil. This ensures ongoing accountability is transparent.

## Communicate to trading partners

Depending upon the business process in scope, and the element of the GS1 standards being implemented, trading partners may need to be informed and engaged. For example, if traceability is being implemented, communicating the need to ensure that GS1 barcodes are applied to all level of product packaging is essential. Likewise if data synchronisation using the Global Data Synchronisation Network (GDSN) or electronic data interchange (EDI) using GS1 standards is being implemented, trading partner current capabilities and implementation timelines will need to be understood. This will allow identification of the first implementation partners.

Engagement of trading partners may occur via group briefings, written communication or one to one meetings dependent upon the preference of the implementing organisation. In the future, regular meetings may occur with key trading partners to ensure initially agreed timelines are met. It is suggested that early, concise and regular communications are made from the healthcare provider to any trading partners in order to clarify the intent of the project and the scope of their participation.

## Put in place a change management plan

For any successful project, effective change management is key. Based on the desired processes, plans for change management should be made by the project team. It is important to identify the stakeholders that should be subject to change management activities. Change management will need to be undertaken with most stakeholders as part of the overall implementation process, i.e., prior to deployment, to ensure key users are ready to act at the time of deployment. Support should continue for an agreed period after deployment to ensure the new processes are able to be used confidently and any issues identified then rectified.

## Outcome

A project with a specific objective has been agreed, clear requirements and realistic deadlines set, and detailed functional specifications completed. The need for external partners is known and trading partners will be briefed as necessary. Change management plans are drafted.

## Step 5: Develop technical solutions and undertake as-is state measures

### Create technical specifications

Using the functional specifications, technical design needs to be finalised and the process to implement changes in the IT systems or hardware capabilities agreed. This may be done in-house, in partnership, if external IT resources are selected or completely outsourced. If done in partnership with external IT resources, it is recommended a change request be submitted to your solution provider for any necessary changes. This will help to ensure the requested functionality is included in mainstream system vs. being stand-alone changes.

Either way, validation of the technicalities regarding the use of GS1 standards is needed, and it is recommended that your local GS1 Member Organisation is engaged to assist. In particular, the GS1 Member Organisation can connect healthcare providers with peers who have implemented similar technologies or solutions. The GS1 Member Organisation can help facilitate the conversations and discussions.

As part of this work, the need for IT system interoperability needs to be understood in detail and agreed.

### Finalise assessment regarding IT upgrade paths

If changes do need to be made to IT hardware or software, perhaps it is sufficient to upgrade or undertake a possible extension of the current IT capabilities. However, a new system could also be purchased. The experience of different hospitals has shown that this is arguably the most important task in the implementation process and due attention should be paid.

If new IT solutions (hardware or software solutions) are to be purchased, it is extremely important to assess the capabilities of those solutions offered and ensure these are in line with GS1 standards. Solutions that may be procured include Enterprise Resource Planning (ERP), Hospital Information Systems (HIS), Warehouse Management Systems (WMS), Electronic Patient Dossiers (EPD) Pharmacy Information Systems (AIS) and Electronic Prescription Systems as well as the associated scanners and printers. Note, when choosing scanners, it is important to source imaging scanners as they are capable of reading both 1D and 2D barcodes.

### As-is state measures

At this point, as-is state measures should be taken. This is to identify the baseline for return on investment calculations that will occur later in the implementation process. It is recommended that measures are captured for approximately 1 month.

### Outcome

The detailed technical specifications for functionality and interoperability are finalised and if necessary, IT upgrade paths are agreed. In addition, the as-is state is measured.
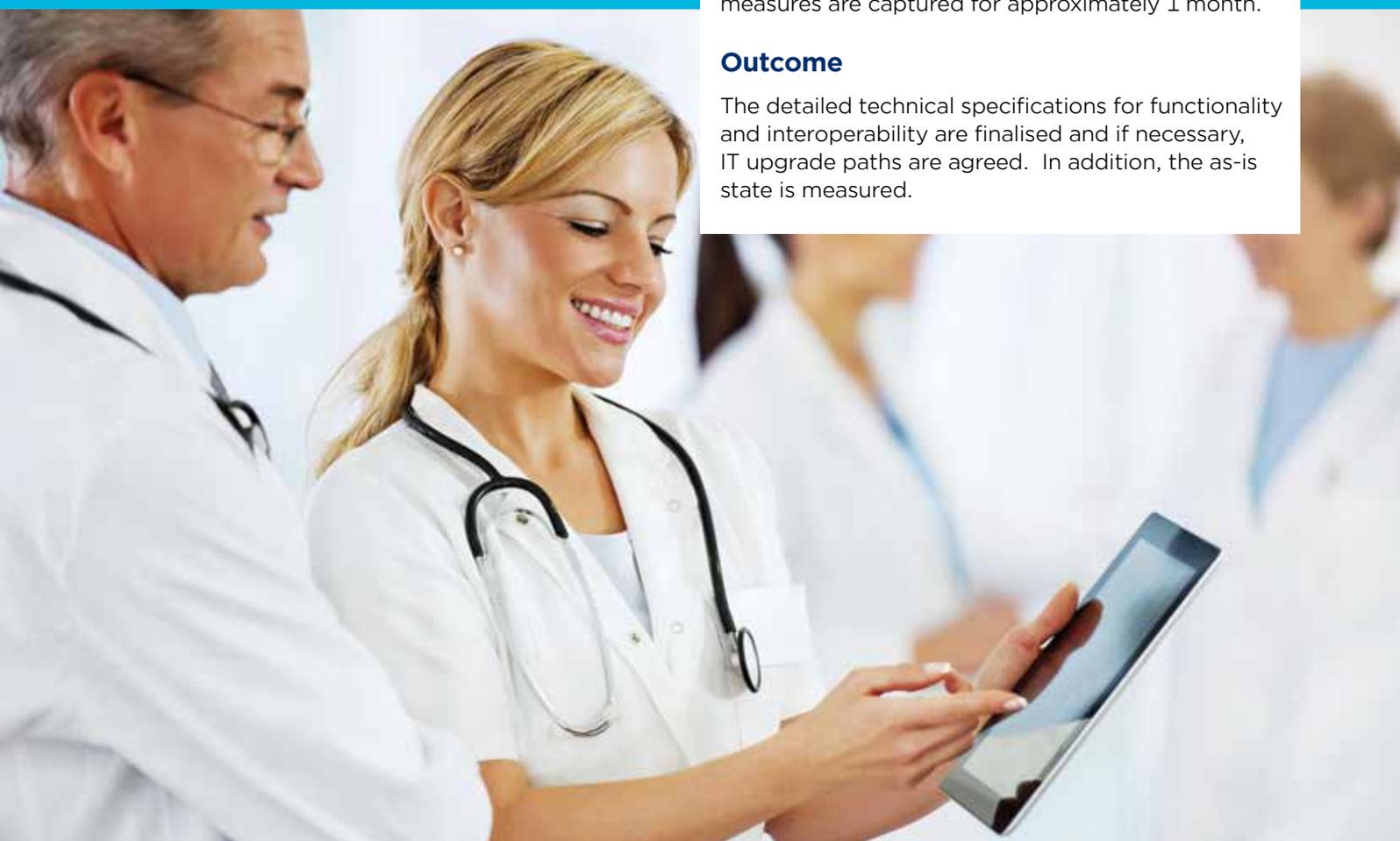
## Step 6: Execute training and create documentation

Training for the eventual business users, as well as, for the development of standard operating and issue escalation processes is essential.  Ensure employees are well informed and trained.  Training material and documents should be developed by the project team and tested with a subgroup of business users for their feedback before broad-scale release.

### Outcome

All necessary training will have been developed and undertaken by the end of this step.



## Step 7: Complete first stage implementation

It is important to ensure that the new processes and technologies are functioning as required.  A small scale implementation will also identify any issues or barriers to be addressed, and allow these to be fixed with minimal impact to your organisation.

### Built and test functionality

The new functionality needs to be built.  Once this is complete, before exposing the new processes to trading partners or other organisational departments, it is important that comprehensive testing has been undertaken.  Ensure test plans are developed and executed.  Once everything is working as expected, it is time to engage other partners.

### Select initial implementation partners

Depending upon the clinical or business process in question, and the GS1 standards element being implemented, the project team should choose a small group of suitable partners for first stage implementation.  These should be sufficiently diverse to allow testing of as many situations as possible and with as many trading partners, as well as, other departments within your organisation.

### Undertake the first implementations

First stage implementations may occur in a test or a live environment.  There should be a plan in place, including scope and timelines.  The findings of this activity will help to further refine any processes. During these first implementations, ensure good support is provided to trading partners and ensure external IT providers have allocated resource to assist.

### Outcome

The first implementation is complete, which will ensure that functionality is operational internally and that processes / functionality with trading partners and other departments is accurate.

Remember to celebrate this milestone! It is an excellent progress and it is important that the various stakeholders are recognised for this achievement.  At this stage, some healthcare providers participate with industry awards that can help shine the spotlight on the project and create momentum so other stakeholders choose to get involved.
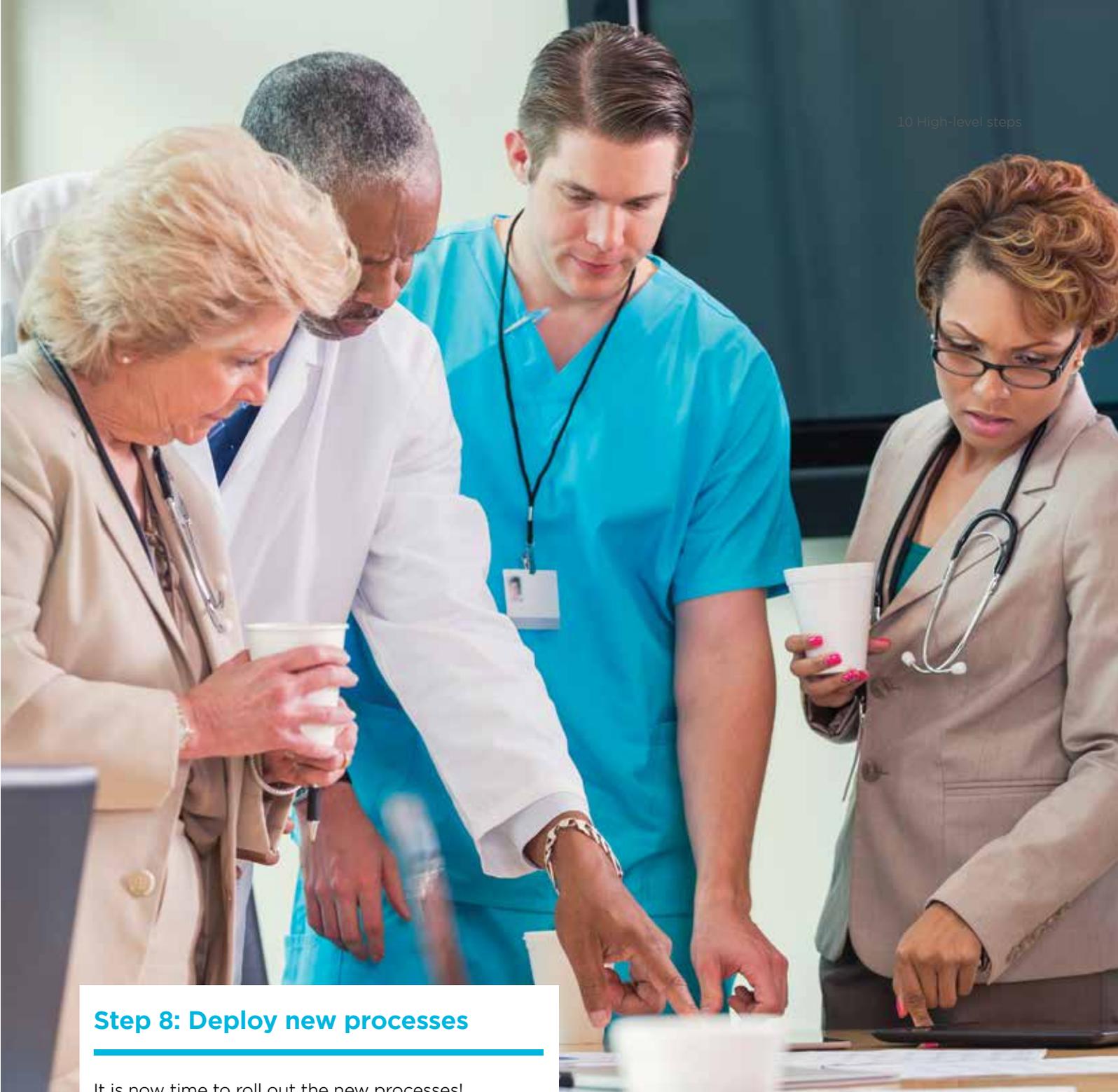
## Step 8: Deploy new processes

It is now time to roll out the new processes!

### Deployment plan

Before undertaking broad-scale deployment, the project team will have documented a deployment plan based on (1) internal capabilities to roll out and (2) capacity / capability of trading partners. Depending upon the element of the GS1 standards being implemented, some trading partners may be undertaking their own implementation projects and hence the organisation's deployment plan will need to be aligned with this. An important part of the deployment plan will be change management activities detailed in step 4.

### Deployment

During the initial phases of deployment, all the monitoring undertaken in step 6 will continue. However, as deployment becomes business as usual this can be decreased. During this stage business users will become responsible for the system and ownership will move from the project team.

### Outcome

The new process is now live and business users are responsible.

## Step 9: Evaluate

After a period of business as usual operation, and when all parties are accustomed to the new processes, to-be state evaluation should occur. This will use the measures identified in step 4 and will be the information needed to calculate return on investment of the implementation. To-be state measurement should occur for the same time period as the as-is state measurement was conducted.

### Outcome

Return on investment can now be calculated and reported to Senior Management.

## Step 10: Monitor, refine and expand

Once the system has been implemented, it is important that there is constant attention paid to its operation. Make sure the management and maintenance of the system remains as an important task to those business users assigned operational responsibility and the hardware, software and databases are kept functional and up to date, so the clinical staff can rely on them.

During monitoring, it is important to consider if the new processes still meet the original objectives.

Periodic checks should be undertaken to ensure business users are adequately trained and the process is also still effective for trading partners. In addition, it is recommended to evaluate the new process annually to make any necessary refinements driven by new developments.

This is now the time to start step 1 again, and identify the next clinical or business process for which GS1 standards will be implemented in the organisation. During steps 9 and 10, your local GS1 Member Organisation will continue to play a supporting role as the project is rolled out further.

### Outcome

Continuous improvement of new processes will be achieved by monitoring and refinement and this will ensure the new processes continue to meet operational user needs.

**About GS1 Healthcare**

GS1 Healthcare is a global, voluntary user community bringing together all healthcare supply chain stakeholders, including manufacturers, distributors, healthcare providers, solution providers, regulatory bodies and industry associations. The mission of GS1 Healthcare is to lead the Healthcare sector to the successful development and implementation of global standards by bringing together experts in Healthcare to enhance patient safety and supply chain efficiencies. GS1 Healthcare members include over 70 leading Healthcare organisations worldwide.

www.gs1.org/healthcare

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