NDC12 Readiness Planning Guide

Industry Planning Guidelines, Project Phases,
and Planning Approaches for NDC12 Implementation

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1 Executive Overview

What's Inside this Guide

1 Planning guidelines based on current industry discussions
2 Five phases of an NDC12 implementation project
3 Time-boxed planning methodology
4 Industry dependency checklist
5 Overview of the NDC12 Readiness Planning Tool

The 12-digit National Drug Code (NDC12) is the FDA's replacement for the current 10-digit National Drug Code format to address long-term code exhaustion and support future product identification. The FDA's Final Rule in March 2026 gave the industry seven years to complete this transition.

Seven years sounds like a long time. Until you start planning.

The FDA's transition to the 12-digit National Drug Code (NDC12) is one of the largest coordinated technology and operational changes the healthcare industry has undertaken in decades. While the regulation itself is straightforward, the implementation is anything but.

NDCs are deeply embedded throughout the healthcare ecosystem. They appear in ERP systems, manufacturing systems, product labels, barcode scanners, pharmacy applications, claims processing, regulatory reporting, analytics platforms, EHRs, data warehouses, custom applications, and countless interfaces connecting one organization to another. Changing the number is often the easy part. Understanding everywhere that number is used is the real challenge.

Initially, discussions focused on:

> ***What will the FDA do?***
> i.e., What requirements would the FDA include in the Final Rule?

Today, the conversation has shifted to:

> ***What do WE do now?***
> *i.e., How should organizations plan and execute an NDC12 implementation within a fixed seven-year window?*

Planning for NDC12 requires more than upgrading software. Organizations must coordinate technical designs, packaging changes, validation activities, trading partner readiness, and years of testing, all within a fixed implementation window. At the same time, many critical industry decisions are still evolving, requiring project plans to adapt as new guidance becomes available.

This guide was written to help organizations answer that question. Rather than focusing on the regulation, it introduces a practical guide (See Appendix 6.6 NDC12 Planning Approach) built from current industry discussions and implementation experience. This guide is organized around three topics:

1. **Planning Guidelines** that help organizations establish realistic planning assumptions

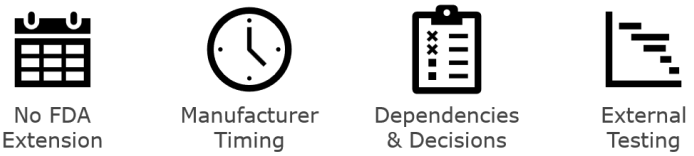


Figure 1 - Key NDC12 Planning Guidelines

2. **Project Phases** that organize the work from assessment through external testing.

Figure 2 - Five phases of an NDC12 implementation project.

3. **Planning Approaches** showing how time-boxed planning can transform a seven-year implementation window into an achievable roadmap.

Figure 3 - Sequential and Parallel Planning

The guide also includes practical appendices covering recommended working groups, current industry dependencies, and an overview of the NDC12 Readiness Planning Tool.

No organization has every answer today, and no implementation plan will be perfect on day one. The objective is not to eliminate uncertainty before you begin. The objective is to start early, understand the work ahead, and build a roadmap that can evolve as the industry moves toward March 2033.

The organizations that begin planning today will have the greatest flexibility tomorrow.

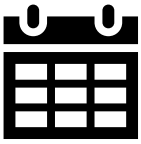
2 Planning Guidelines

Learnings from Industry Discussions

Recent industry discussions have surfaced several practical planning assumptions that can help organizations build more realistic NDC12 plans.

These are not regulatory requirements. They are planning guidelines based on discussions occurring across the healthcare ecosystem.

2.1 Do Not Expect an Extension



FDA representatives participating in recent industry discussions have consistently reinforced a simple message: organizations should not assume additional time will be granted.

The transition to a 12-digit NDC is being driven by the industry's need for additional numbering capacity. Eventually, the available pool of numbers will be exhausted.

Organizations should build plans around the published timeline rather than hypothetical extensions. Planning around the assumption that the FDA will provide more time creates unnecessary risk and reduces the time available for assessment, upgrades, testing, and trading partner coordination.

*The US assigns approximately 1,000 new NDC labeler codes each year. During COVID-19, approximately **7,000 labeler codes** were assigned, illustrating how quickly the inventory can be consumed during a major public health event.*

Another pandemic or similar emergency could rapidly accelerate code exhaustion, reinforcing the importance of completing the transition to the 12-digit NDC within the seven-year window.

2.2 Manufacturers Have Less Time

The FDA implementation deadline is March 2033. At first glance, this appears to give manufacturers 7 years to prepare. In practice, many manufacturers will need to act sooner.

The Final Rule includes a 3-year transition period ending in March 2036 to allow products bearing 10-digit NDC labeling to move through the supply chain while manufacturers complete the transition. After that transition period, organizations should plan on supporting only products labeled with the 12-digit NDC.

That creates an important planning challenge. Manufacturers must determine when to begin producing 12-digit labeled products so existing 10-digit inventory can be depleted before the transition period ends. Waiting too long increases the risk that compliant, unexpired product remains in the supply chain after the transition window and may need to be removed.

The optimal transition date will vary by product. Shelf life, inventory levels, production schedules, and distribution patterns all influence when manufacturers should begin introducing 12-digit-labeled products. For many manufacturers, the practical deadline will arrive earlier than the regulatory deadline.

2.3 External Testing May Require Years, Not Months

NDC12 is an industry-wide initiative. Success depends on information flowing correctly between manufacturers, repackagers, distributors, pharmacies, providers, payers, regulators, software vendors, and countless trading partners. Upgrading systems and labels within a single organization is only part of the solution. Those systems and new 12-digit labels must also work reliably with every external partner.

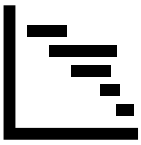
Recognizing the scope of this challenge, industry participants have proposed an external testing period during the latter portion of the seven-year implementation timeline. The objective is to give organizations sufficient time to validate transactions, resolve interoperability issues, and coordinate with trading partners before the implementation deadline.

At the time of writing, this proposal has not yet been adopted by the FDA.

Nonetheless, even without FDA sponsorship of this testing, some form of external testing must occur. Without a structured testing period, organizations risk reaching the implementation deadline with limited end-to-end validation across the healthcare ecosystem. NDC12 is simply too broad and interconnected to assume that every system will work correctly the first time it is turned on.

Organizations should expect external testing to become a major activity in any NDC12 implementation program.

2.4 Dependencies and Industry Decisions Matter



Not every planning assumption is within an organization's control.

Many important decisions continue to evolve across the industry, including guidance, standards, reporting requirements, and trading partner readiness. These dependencies will influence project scope, sequencing, testing, and implementation timing.

These dependencies are summarized in Appendix 6.2 Industry Dependencies. The list of dependencies should be reviewed during the Assessment phase and revisited as new guidance and industry decisions emerge.

Organizations should expect their plans to evolve as dependencies become clearer. The objective is not to wait for every answer. The objective is to identify the open items early, assign ownership, and track the decisions that could affect the NDC12 roadmap.

3 Project Phases

The Five Phases of an NDC12 Project

The planning guidelines establish the guardrails for the work. The next question is more practical: ***"What does an NDC12 project actually look like?"*** Although implementation details will vary by organization, most NDC12 initiatives can be organized into five major phases.

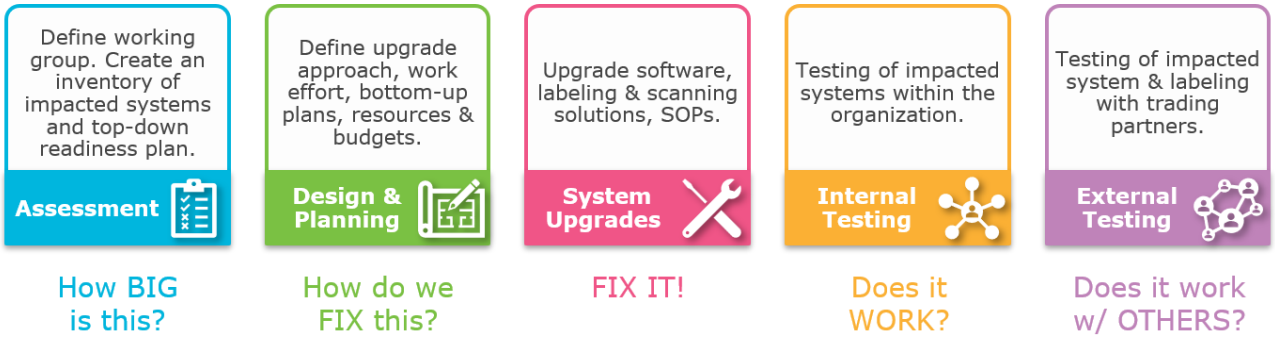
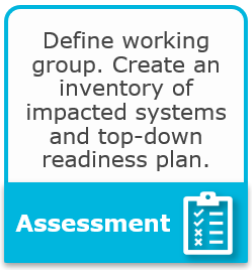


Figure 4 - Five phases of an NDC12 implementation project.

3.1 Phase 1: Assessment



How BIG is this?

With only seven years to complete the implementation, do not wait for a perfect plan. Start the assessment now. New systems, dependencies, and questions will surface along the way. That is expected. What matters is building enough understanding to move forward. Every month lost is one less month available for planning, upgrades, and testing.

The goal of the Assessment phase is not to solve every problem. It is to understand the size of the problem and establish a practical starting point for the project. This phase produces three key activities:

3.1.1 Establish an NDC12 Working Group

Form a small cross-functional team responsible for coordinating the assessment, identifying stakeholders, and driving the readiness effort across the organization. See Appendix: 6.1 Forming the Working Group for recommendations on which departments should be initially involved.

3.1.2 Build an Inventory of Impacted Systems

Develop a high-level inventory of the applications, databases, interfaces, reports, business processes, and trading partner connections that use or depend on the National Drug Code. The inventory does not need to be complete. Its purpose is to identify the areas most likely to require additional analysis.

3.1.3 Develop an NDC12 Readiness Plan

Using the information gathered during the assessment, develop a high-level NDC12 Readiness Plan (aka, "Readiness Plan") that identifies major workstreams, planning assumptions, key dependencies, estimated timelines, and organizational risks. The Readiness Plan is not the final project plan. It is the foundation upon which detailed departmental implementation plans will be built.

NDC12.com offers a free NDC12 Readiness Planning Tool to accelerate planning. The tool provides users with prebuilt templates for project phases, planning assumptions, and dependencies.

See Appendix 6.3 Overview of NDC12 Readiness Planning Tool

3.2 Phase 2: Design and Planning

How do we fix this?

Once the assessment has identified impacted systems, stakeholders, and a high-level Readiness Plan, the next step is developing detailed implementation plans.

This phase transforms the Readiness Plan into an executable program. Instead of one enterprise-level roadmap, organizations develop a collection of coordinated project plans owned by departments and workstreams. Together, those plans roll up into the master implementation plan.

3.2.1 Design Considerations

Technical designs must be established before implementation can begin. Some designs will focus on software modifications, databases, interfaces, and data exchanges. Others will extend into operational processes such as product labeling, barcode generation, printing, scanning, packaging, and validation. The objective is to define how each affected system and business process will support the 12-digit NDC.

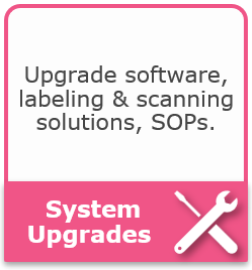
3.2.2 Time-Boxed Planning

The FDA implementation deadline is fixed. Departmental plans cannot be developed in isolation or allowed to expand whenever new work is discovered. Each plan must align with the enterprise Readiness Plan and with the plans managed by other departments.

This is where time-boxed planning becomes important. The Phase 1 Readiness Plan provides the top-down view. Phase 2 turns that view into detailed project plans with milestones, dependencies, resources, and expected completion dates. Those plans may be managed in Microsoft Project, Jira, Smartsheet, Excel, or other tools, but the work still needs to roll into one master plan.

Organizations also need a process to verify progress and identify problems early. Waiting until testing begins to discover that a critical task has fallen behind leaves little room to recover. Regular status reviews, milestone tracking, dependency management, and executive reporting are essential to keeping the overall program on schedule.

3.3 Phase 3: System Upgrades



Fix it.

This phase is where planning becomes execution.

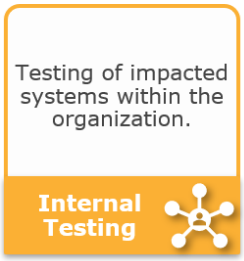
Organizations may need to modify enterprise applications, databases, interfaces, APIs, reports, data warehouses, barcode generation, printing systems, scanning devices, labeling systems, manufacturing equipment, regulatory reporting, and operational procedures. Every place that creates, stores, exchanges, displays, prints, or scans an NDC should be evaluated and updated as necessary.

NDC12 requires coordination across both business and technical teams. Software upgrades must remain aligned with packaging changes. Label designs must support new barcode requirements. Business processes, training materials, standard operating procedures, and supporting documentation may also require updates before systems can be placed into production.

A unique NDC12 challenge is managing the transition between two numbering formats. Organizations will need to support both 10-digit and 12-digit NDCs while products labeled with the legacy format continue moving through the supply chain. Systems, integrations, reports, and business processes must be designed to support that transition without disrupting daily operations.

The scope of this phase will vary by organization. For some, the effort may involve dozens of systems. For others, it may affect hundreds of applications, interfaces, and operational processes. Regardless of scale, disciplined change management and close coordination across workstreams are essential to keeping implementation aligned with the master plan.

3.4 Phase 4: Internal Testing



Does it work?

Internal testing verifies that applications, interfaces, databases, reports, labels, barcodes, and operational processes can successfully support the 12-digit NDC while continuing to operate reliably throughout the transition period. For many organizations, this means confirming that systems can correctly process both 10-digit and 12-digit NDCs wherever dual-format support is required.

This phase should validate more than software functionality. End-to-end business processes, data integrity, reporting, barcode scanning, label generation, and system integrations should all be tested to ensure that changes made in one area do not create unintended issues elsewhere.

The objective is to identify and resolve defects before involving external trading partners. The more issues discovered during internal testing, the more productive and efficient external testing will become.

3.5 Phase 5: External Testing

Does it work with others?

The objective of this phase is to verify interoperability across the healthcare ecosystem. Products, transactions, electronic messages, reports, labels, barcodes, and business processes must function correctly between manufacturers, distributors, repackagers, pharmacies, providers, payers, regulators, software vendors, and other trading partners.

Unlike internal testing, success during this phase depends on the readiness of multiple organizations. A system may function perfectly within one company but fail when exchanging data or labels with an external partner whose systems, business rules, or implementation schedule differ. These interoperability issues are often difficult to predict and can only be identified through coordinated end-to-end testing.

For that reason, many industry participants have proposed a multi-year external testing period before the March 2033 implementation deadline. The goal is to provide sufficient time for organizations to validate transactions, resolve interoperability issues, and coordinate implementation activities across the supply chain before production cutover.

Systems rarely fail in isolation. They fail at the connection points between organizations. The objective of external testing is to identify and resolve those issues before they affect patients, providers, or the pharmaceutical supply chain.

4 Planning Approaches

Sequential Planning vs. Parallel Planning

Once organizations understand the project phases, the next challenge is determining how the work fits into the available timeline.

Two planning approaches are commonly used.

4.1 Sequential Planning

Sequential Plan

- Tasks start only **after** the previous task completes.
- **Academic/Purist** planning approach
- **Clearest view** to highlight critical timelines

Figure 5 - Sequential Planning Attributes

In a sequential plan, each phase begins only after the previous phase has been completed. Assessment is completed before planning begins.

Planning is completed before implementation begins. Implementation is completed before testing begins.

This approach provides the clearest view of how much time a project may actually require. It is often the best way to identify critical path activities and understand schedule risk.

The downside is that many organizations may discover that a fully sequential plan extends beyond the available timeline. Additionally, in the real world, some overlap between tasks is normal and expected.

4.2 Parallel Planning

Parallel Plan

- Tasks can start **before** a previous task is completed.
- **Real-world** planning approach
- **Realistic view** but can obscure critical timelines

Figure 6 - Parallel Planning Attributes

In a parallel plan, certain activities begin before earlier activities are completely finished. Assessment may still be underway while planning begins.

Planning activities may continue while portions of implementation are already in progress.

Testing preparation may begin before all upgrades are completed.

This approach more closely reflects how large transformation programs are executed in the real world.

The benefit is schedule compression. The challenge is increased complexity and coordination.

4.3 Why Both Approaches Matter

Organizations should not view sequential and parallel planning as competing alternatives. Both serve an important purpose at different stages of the project and for different tasks.

Sequential planning provides the clearest picture of the work ahead. It helps organizations understand the major workstreams, identify dependencies, estimate the project's true duration, and determine the critical path. In other words, it answers the question, ***"How long will this really take?"***

Parallel planning answers the question, ***"How does this fit inside the box?"*** It begins with that understanding and works backward from the implementation deadline. Because NDC12 is a time-boxed initiative with a fixed regulatory deadline, organizations must determine where activities can safely overlap, where additional resources may be required, and how departmental plans can be coordinated to complete the work on time.

One approach measures the effort. The other optimizes the schedule. Successful NDC12 programs require both.

4.4 Turning Planning Concepts into a Roadmap

Understanding sequential and parallel planning is useful, but the value comes from applying those concepts to a real implementation roadmap.

The key is dependency management. Most project management tools allow one task to be linked to another task. In a simple sequential plan, a successor task begins only after its predecessor is complete.

Parallel planning keeps the dependency in place but uses an offset when it is safe for the next activity to begin before the prior activity is fully complete. The dependency is not removed. The start point is adjusted based on what the work actually requires.

The example below shows how this works. In the sequential plan, each task begins after the previous task ends. Both dependencies use a zero-month offset, so the full effort takes 29 months.

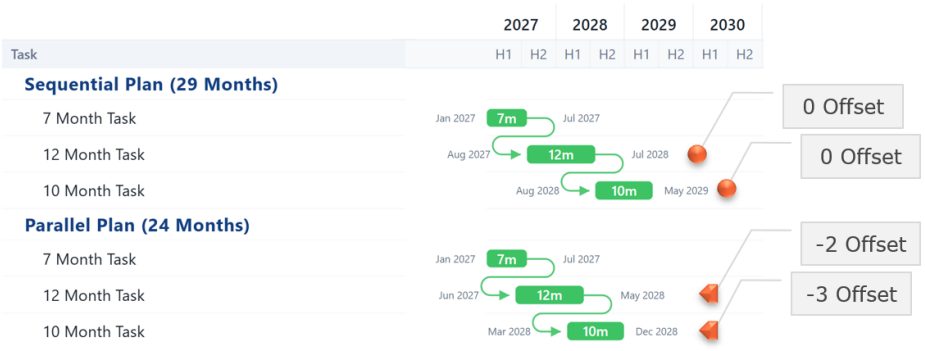


Figure 7 - Example of Sequential and Parallel Planning Using Dependency Offsets

Spreadsheets can still be useful for task lists and status reporting, but they are not ideal for managing large numbers of dependencies across departments. As the number of workstreams grows, dependency-aware tools become more important. The NDC12 Readiness Planning Tool is one example of this approach (See Appendix 6.3 Overview of NDC12 Readiness Planning Tool).

Project management tools that support task dependencies and offsets make this analysis much easier. Rather than manually recalculating schedules, project managers can model alternatives, evaluate what-if scenarios, and immediately understand how changes affect the overall implementation timeline.

This is the essence of time-boxed planning. Organizations first estimate how long the work would take if performed sequentially. They then identify where dependencies can safely overlap to fit the work within the fixed implementation window. Every overlap should be supported by a technical or business justification, not simply a desire to shorten the schedule.

The scope has not changed. The same three tasks still require the same amount of work. The schedule is compressed by identifying where activities can proceed in parallel without ignoring real dependencies.

In the parallel plan, the same dependencies remain in place, but offsets are applied. The second task begins two months before the first task is complete. The third task begins three months before the second task finishes. The work overlaps where it is reasonable to do so, reducing the schedule from 29 months to 24 months.

5 Moving Forward

The industry now has a Final Rule. What it needs next are practical implementation plans.

No organization has every answer today. Many dependencies remain unresolved, and additional industry guidance will continue to emerge. That is normal for a transformation of this size.

Organizations do not need perfect information before they begin planning. They need enough information to understand the assumptions, phases, dependencies, and timelines that will shape the journey ahead.

The NDC12 Planning Framework presented in this guide provides one practical approach for organizing that work and adapting as additional guidance becomes available.

6 Appendix

6.1 Forming the Working Group

6.1.1 Getting Started

The initial working group is established during the Assessment phase. At this point, it does not need representatives from every department. Start with the functions most likely to be affected and expand the team as the assessment progresses. For many organizations, the initial working group includes:

- **Executive Sponsor**: Provides funding, removes roadblocks, and establishes organizational priority.
- **Program Management (PMO)**: Coordinates activities, timelines, risks, and communication across departments.
- **Information Technology**: Identifies impacted applications, databases, interfaces, integrations, and infrastructure. This should include system architecture, EDI, and master data management resources.
- **Regulatory Affairs / Quality**: Interprets FDA requirements, monitors evolving regulatory guidance, and identifies validation requirements for regulated systems and processes. Depending on your organization, this may also include Legal or Compliance.
- **Manufacturing / Operations**: Assesses impacts to production systems, packaging, labeling, serialization, and shop floor processes.
- **Supply Chain / Commercial Operations**: Assesses inventory strategy, distribution, customer-facing processes, product catalogs, ordering, and trading partner readiness.
- **Procurement / Vendor Management**: Coordinates with software vendors, service providers, and implementation partners.

The objective of the working group is not to solve every problem during the Assessment phase. Its purpose is to identify impacted systems, business processes, owners, dependencies, and potential risks. That information becomes the foundation for planning the remaining phases of the project.

6.1.2 Who Owns NDC12?

One of the first questions organizations ask is who should lead the initiative. The answer is usually **no one department.**

NDC12 spans regulatory, business, operational, and technology domains. In most organizations, the project should have an executive sponsor and be managed as a cross-functional enterprise initiative rather than being owned solely by IT or Regulatory Affairs

6.1.3 Working Group vs. Steering Committee

Organizations should distinguish between the NDC12 Working Group and the NDC12 Steering Committee. Both are important, but they serve different purposes.

The NDC12 Working Group is established during the Assessment phase. Its role is to identify impacted systems, business processes, owners, dependencies, and risks. This group does the early discovery work and develops the initial NDC12 Readiness Plan.

The NDC12 Steering Committee should be established as the effort moves from assessment into Design and Planning. Its role is to provide executive oversight, approve funding, resolve cross-functional issues, monitor progress, and ensure the program remains aligned with organizational priorities.

In simple terms, the Working Group helps determine the size of the problem. The Steering Committee helps govern the response.

6.2 Industry Dependencies

The dependency list below reflects early industry planning discussions and will continue to evolve as guidance, standards, and ownership decisions mature. It is intended as a planning aid, not a final regulatory checklist.

Organizations should review these dependencies during the Assessment phase and update their Readiness Plan as new decisions are made. Where appropriate, assign an owner to monitor each dependency and assess its impact on the implementation roadmap.

The list of dependencies below was the result of a 2-day workshop hosted by Leavitt Partners with 60 different industry participants. This list is still being developed and refined. New dependencies, owners, and target readiness dates continue to be identified.

Dependency	Description
FDA Transition Inventory Guidance	Clarifications are needed from the FDA on how to manage products labeled with NDC10 (i.e., Transactional Inventory) before the deadline.
HIPAA/11-digit Guidance	HIPAA regulations currently require the use of an 11-digit NDC in many healthcare transactions. HIPAA rules and implementation guidance must be updated and clarified to support 12-digit NDCs, ensuring that claims, reimbursement, and related healthcare transactions continue to function correctly.
Linear Barcode Guidance	Current barcode standards cannot accommodate the 12-digit NDC. Guidance is needed on transitioning to 2D barcodes or an alternative 1D standard.
NCPDP Prescribing Standards	NCPDP develops the standards used for electronic prescribing between providers, pharmacies, and PBMs. These standards must be updated to support 12-digit NDCs so prescription data can continue to be exchanged accurately throughout the NDC12 transition.
NCPDP Billing Standards	NCPDP develops the standards used for pharmacy claims and billing transactions between pharmacies, PBMs, and payers. These standards must be updated to support 12-digit NDCs so drug claims can be processed, adjudicated, and reimbursed correctly after the NDC12 transition.
Compendia Upgraded	Drug compendia (such as First Databank, Medi-Span, and RxNorm) provide the drug reference data used by prescribing, dispensing, billing, and clinical systems. These compendia must be updated and available in production with 12-digit NDC support before downstream systems can accurately process and exchange NDC12 data.
X12 Standards	X12 develops the HIPAA standards used for healthcare claims, payments, and reimbursement transactions. These standards must be updated to support 12-digit NDCs so drug-related information can continue to flow correctly between providers, payers, and government programs.
HDA Case Label and EDI Guidelines	HDA (Healthcare Distribution Alliance) case label and EDI guidelines define how product information is identified and exchanged between manufacturers, distributors, and downstream trading partners. These guidelines must be updated to support 12-digit NDCs so products can be labeled, scanned, and transacted consistently throughout the pharmaceutical supply chain.
FDA SPL XML File	FDA Structured Product Labeling (SPL) XML files are used by manufacturers to submit drug listing and product information to the FDA. These XML specifications must be updated to support 12-digit NDCs so products can be registered, maintained, and exchanged correctly within FDA systems.

Dependency	Description
DailyMed Updated	DailyMed is the National Library of Medicine's online repository for FDA-approved drug labeling information. DailyMed must be updated to support and display 12-digit NDCs so healthcare providers, pharmacies, and other stakeholders can accurately access product information throughout the NDC12 transition.
RxNorm Updated	RxNorm is the National Library of Medicine's standardized drug vocabulary that links drug names, ingredients, and identifiers across healthcare systems. RxNorm must be updated to support 12-digit NDCs so EHRs, e-prescribing systems, pharmacies, and other clinical applications can accurately map and exchange drug information.
Immunization Systems (IIS), VTrckS	Immunization Information Systems (IIS) and CDC's VTrckS vaccine ordering system use NDCs to identify, track, order, and report vaccines. These systems must be updated to support 12-digit NDCs so vaccine inventory, administration records, public health reporting, and ordering processes continue to function correctly after the NDC12 transition.
PDMP Systems Updated	Prescription Drug Monitoring Programs (PDMPs) are state-run systems that track the prescribing and dispensing of controlled substances to support patient safety and combat drug misuse. These systems must be updated to support 12-digit NDCs so prescription reporting, monitoring, analytics, and interstate data sharing continue to function correctly after the NDC12 transition.
CMS Systems Updated	CMS (Centers for Medicare & Medicaid Services) establishes many of the reimbursement, claims processing, and healthcare transaction requirements that rely on NDC identifiers. CMS guidance is needed to clarify how 12-digit NDCs will be used in claims, billing, reimbursement, and public healthcare programs so the industry can implement consistent and compliant solutions.
DEA ARCOS, CSOS Reporting Systems	DEA reporting systems, including ARCOS, CSOS, and related controlled substance reporting programs, use NDC identifiers to track and monitor controlled substances. DEA guidance and system updates are needed to support 12-digit NDCs so manufacturers, distributors, pharmacies, and regulators can continue to report and monitor controlled substances accurately.

6.3 Overview of NDC12 Readiness Planning Tool

6.3.1 Why a Readiness Planning Tool?

One key deliverable from the Assessment phase is a top-down Readiness Plan. While this deliverable can be created with spreadsheets or traditional project management software, organizations can shorten the Assessment phase by using a planning tool specifically designed for NDC12.

The NDC12 Readiness Planning Tool provides a structured starting point based on current industry planning assumptions. Rather than building a schedule from a blank page, organizations can begin with preconfigured templates and customize them to reflect their own systems, priorities, and implementation strategy.

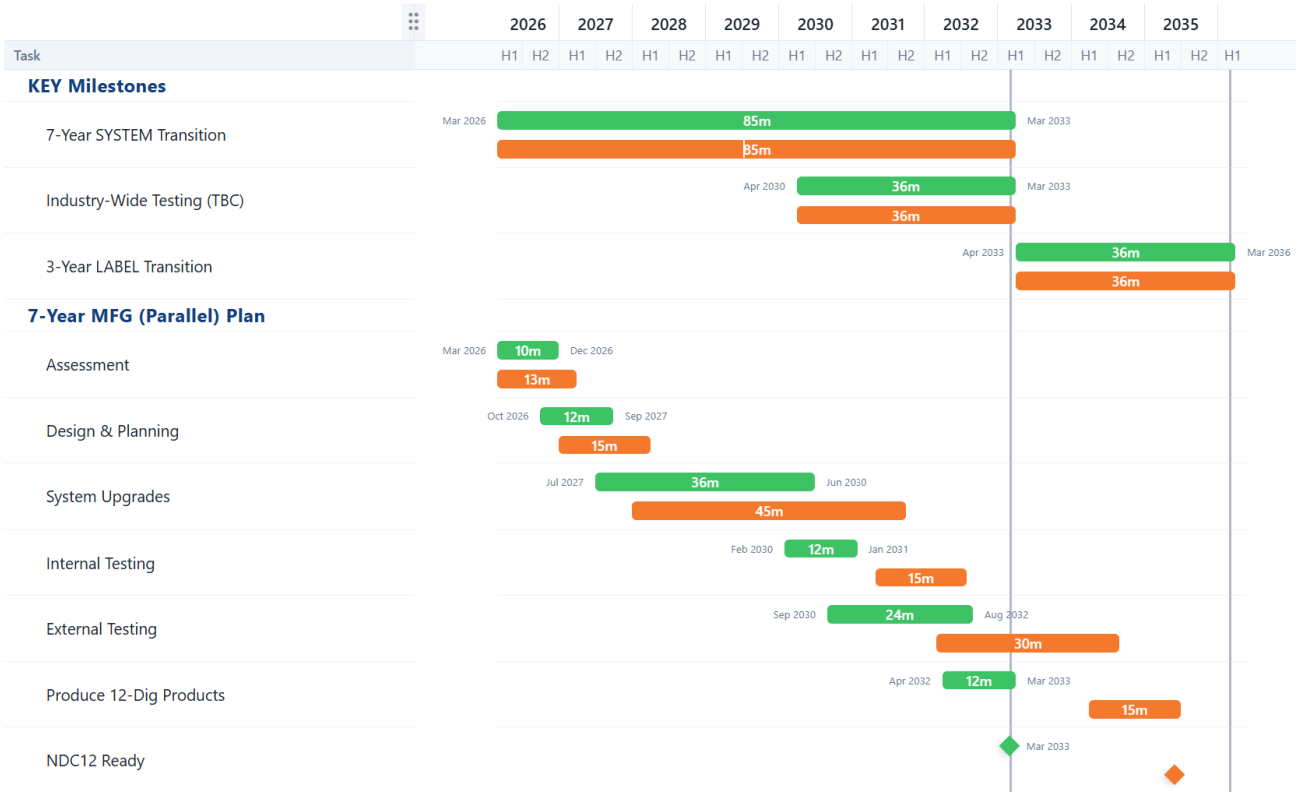


Figure 8 - Sample Gantt Chart from NDC12.com Readiness Planning Tool

6.3.2 NDC12 Planning Templates

The NDC12 Readiness Planning Tool currently has the following templates as of the writing of this document. Additional templates will be added over time. To see the latest templates and features, go to NDC12.com

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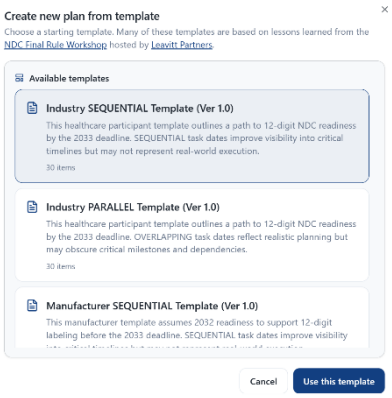

Figure 9 - Planning Templates from NDC12.com Readiness Planning Tool

- **Industry SEQUENTIAL Template** — Healthcare participant template outlines a path to 12-digit NDC readiness by the 2033 deadline.
- **Industry PARALLEL Template** — Healthcare participant template outlines a path to 12-digit NDC readiness by the 2033 deadline.
- **Manufacturer SEQUENTIAL Template** — Manufacturer template with 2032 readiness to support 12-digit labeling before the 2033 deadline.
- **Manufacturer PARALLEL Template** — Manufacturer template with 2032 readiness to support 12-digit labeling before the 2033 deadline.
- **Empty Template** — Empty template with no predefined tasks. Create tasks and dependencies as needed.

6.3.3 Building Your Readiness Plan

The objective of the tool is not to produce a detailed departmental project plan. Instead, it helps organizations create a top-down Readiness Plan for the Assessment phase that identifies:

- Major workstreams
- Key milestones
- Planning assumptions
- Estimated timelines

As the assessment evolves, the Readiness Plan can be updated and refined before detailed departmental planning begins. A unique feature of the NDC12 Readiness Plan Tool is the ability to assign confidence levels to all tasks. This feature allows organizations to quickly assess the potential risk and impact of key tasks and milestones.

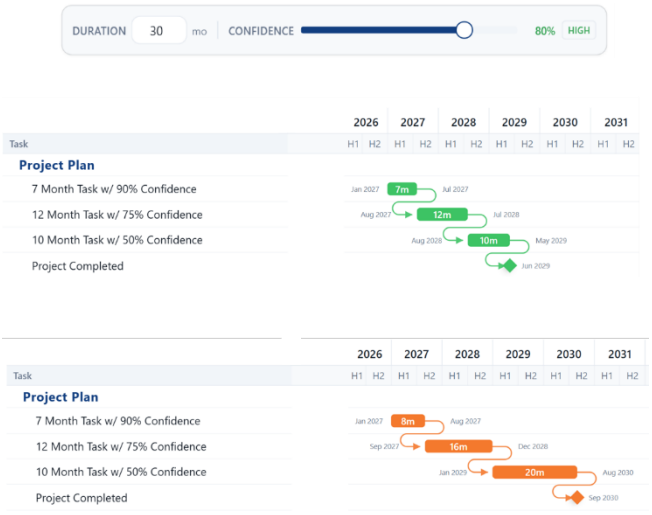

Figure 10 - Examples of Best/Worst Case plans from NDC12.com Readiness Planning Tool

6.3.4 Supporting Time-Boxed Planning

The tool supports dependency-aware planning. Tasks can be linked using Finish-to-Start, Start-to-Start, and Finish-to-Finish relationships. Each dependency can also include positive or negative month offsets, allowing project teams to evaluate where work can safely overlap without removing critical dependencies.

This makes it possible to compare sequential and parallel implementation strategies and evaluate "what-if" scenarios before committing to a project schedule.

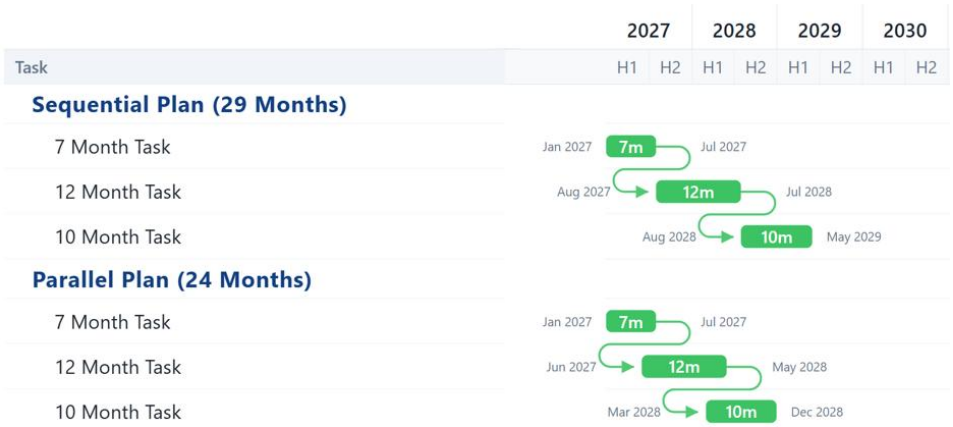

Figure 11 - Example of an NDC12 Time-Box Plan

6.3.5 A Starting Point, Not the Final Plan

The Readiness Planning Tool was designed to accelerate the Assessment phase by helping organizations create a realistic Readiness Plan.

As implementation progresses, individual departments will typically continue detailed planning using their preferred project management tools. The Readiness Plan then serves as the enterprise roadmap, aligning departmental efforts and providing leadership with a consolidated view of overall readiness.

Additional information, including step-by-step instructions for using the application, is available in the Readiness Planning User Guide.

6.4 Acknowledgments

This guide reflects insights gained through collaborative industry discussions focused on NDC12 readiness and implementation planning. Special acknowledgments are extended to the organizations below, which were instrumental in shaping this planning guide.

6.4.1 Leavitt Partners

Special thanks to Leavitt Partners for facilitating multi-stakeholder workshops that helped identify implementation challenges, planning assumptions, and cross-industry dependencies. Their leadership helped to shape many of the ideas that went into this planning guide.

Those discussions and continued coordination across manufacturing, distribution, care delivery, reimbursement, and regulatory will continue through the NDC Coordination and Implementation Forum (**www.NDCForum.org**).

This forum will be one of the **most important sources of information** on NDC12. Bookmark this site and join the forum to keep up to date on the latest changes.

6.4.2 GS1 US Healthcare

GS1 US Healthcare hosts weekly industry forums to discuss the details of NDC12.

Their leadership in driving consistent standards provides ongoing course-correction and clarification regarding the impact of NDC12 on barcodes, labels and data exchange standards.

If you are a member of GS1 Healthcare, then you should join the NDC Format Work Group, which is part of GS1's US Healthcare Industry Initiative: **https://www.gs1us.org/industries-and-insights/by-industry/healthcare/industry-initiative/workgroups**

6.5 Standard Terminology

Term	Definition
10-digit NDC	The current FDA National Drug Code format used before the transition to NDC12. This guide uses **10-digit NDC** rather than **NDC10**.
12-digit National Drug Code (NDC12)	The FDA's new National Drug Code format established to address long-term code exhaustion. After the first reference, this guide uses the abbreviation **NDC12**.
Assessment Phase	The first phase of an NDC12 project. It focuses on understanding the size of the effort by establishing a Working Group, identifying impacted systems, and developing a Readiness Plan.
Critical Path	The sequence of dependent activities that determines the shortest possible project duration. Delays to critical path activities delay the overall project.
Departmental Project Plan	A detailed implementation plan developed by an individual department or workstream. Departmental plans roll up into the Master Implementation Plan.
Dependency	A relationship between two project activities where one activity affects the timing or completion of another.
Design and Planning Phase	The second phase of an NDC12 project. During this phase, the Readiness Plan evolves into detailed departmental project plans and a coordinated Master Implementation Plan.
Executive Sponsor	A senior executive responsible for organizational sponsorship, funding, removing roadblocks, and ensuring the success of the NDC12 program.
External Testing Phase	The phase in which organizations verify interoperability with manufacturers, distributors, pharmacies, providers, payers, regulators, software vendors, and other trading partners.
Final Rule	The FDA regulation establishing the transition to the 12-digit National Drug Code and its implementation timeline. (URL: https://www.fda.gov/drugs/electronic-drug-registration-and-listing-system-edrls/national-drug-code-format?utm_medium=email&utm_source=govdelivery)
Industry Dependencies	External decisions, standards, regulatory guidance, and trading partner activities that may influence an organization's implementation strategy or schedule.
Internal Testing Phase	The phase in which organizations validate that their own systems and business processes correctly support NDC12 before testing with external organizations.
Interoperability	The ability of independent systems and organizations to accurately exchange, interpret, and use NDC12-related information across the healthcare ecosystem.
Master Implementation Plan	The enterprise project plan that integrates departmental workstreams, milestones, dependencies, resources, and timelines into a single coordinated roadmap.
NDC12 Readiness Plan	A top-down planning document created during the Assessment phase that identifies major workstreams, planning assumptions, key dependencies, estimated timelines, and organizational risks. It is the foundation for detailed departmental planning.
NDC12 Readiness Planning Tool	A planning tool available through NDC12.com that helps organizations create an initial Readiness Plan using industry-based templates, project phases, dependencies, and planning assumptions.
Offset	A scheduling adjustment applied to a dependency. A negative offset allows a successor activity to begin before its predecessor is fully complete when it is safe to do so. A positive offset delays the start of the successor activity.

Term	Definition
Parallel Planning	A planning approach in which appropriate activities overlap to reduce the overall implementation schedule while maintaining required dependencies.
Sequential Planning	A planning approach in which activities are scheduled one after another to estimate the true duration and critical path of the project.
Steering Committee	An executive governance body established during the Design and Planning phase. The Steering Committee provides strategic oversight, approves funding, resolves cross-functional issues, monitors program progress, and helps ensure the project remains aligned with organizational priorities.
System Upgrades Phase	The phase in which organizations implement changes to software, databases, interfaces, labels, barcodes, operational procedures, and supporting systems.
Time-Boxed Planning	A planning methodology that begins with a fixed implementation deadline and organizes work to fit within the available time.
Trading Partner	An external organization that exchanges products, transactions, labels, reports, or other NDC-related information with another organization.
Working Group	A cross-functional team established during the Assessment phase. The Working Group identifies impacted systems, business processes, owners, dependencies, and risks, and develops the initial NDC12 Readiness Plan.
Workstream	A major area of project activity, typically owned by a department or functional team, such as ERP, labeling, manufacturing, regulatory affairs, or supply chain.

6.6 NDC12 Planning Approach

This guide presents a practical approach for planning and managing an NDC12 implementation. The approach organizes the project into a series of related concepts that build upon one another, from initial assessment through external testing.

6.6.1 Planning Framework

The Planning Framework below summarizes the methodology presented throughout this guide and provides a common vocabulary for discussing NDC12 implementation.

Concept	Purpose	Primary Deliverable
Planning Guidelines	Establish planning assumptions based on current industry discussions.	Planning assumptions
Assessment	Understand the scope of the effort by identifying impacted systems, stakeholders, and dependencies.	NDC12 Readiness Plan
Design and Planning	Develop technical designs and detailed departmental implementation plans that align with the Readiness Plan.	Master Implementation Plan
System Upgrades	Modify applications, interfaces, labels, barcodes, operational procedures, and related systems to support NDC12.	Updated systems and business processes
Internal Testing	Validate that systems and business processes function correctly within the organization.	Internally validated solution
External Testing	Verify interoperability with trading partners and the broader healthcare ecosystem.	Production-ready implementation

6.6.2 Relationship Between Key Planning Artifacts

The planning process evolves through a series of increasingly detailed deliverables.

Planning Artifact	Purpose
Working Group	Identifies impacted systems, stakeholders, dependencies, and risks during the Assessment phase.
NDC12 Readiness Plan	Provides an enterprise-level view of major workstreams, planning assumptions, dependencies, estimated timelines, and organizational risks.
Departmental Project Plans	Define detailed tasks, milestones, resources, and schedules for each functional area.
Master Implementation Plan	Integrates departmental plans into a single enterprise roadmap used to manage execution and monitor progress.
Steering Committee	Provides executive governance, funding oversight, issue resolution, and strategic direction throughout implementation.

6.6.3 Planning Methodology

This guide describes two complementary planning approaches.

Planning Approach	Primary Objective
Sequential Planning	Estimate the project's true duration, identify dependencies, and determine the critical path.
Parallel Planning	Compress the implementation schedule by allowing appropriate activities to overlap while maintaining required dependencies.
Time-Boxed Planning	Organize and optimize work so the implementation can be completed within the FDA's fixed implementation window.

6.6.4 Core Principles

This planning approach is built upon several principles that appear throughout this guide.

- Begin planning before every dependency has been resolved.
- Build an enterprise Readiness Plan before creating detailed departmental schedules.
- Base implementation decisions on realistic planning assumptions rather than optimistic timelines.
- Recognize that successful implementation depends on coordination across the healthcare ecosystem, not simply within one organization.
- Manage dependencies proactively and monitor progress throughout the project.
- Treat the Readiness Plan as a living document that evolves as additional information becomes available.

6.6.5 Document Information

6.6.5.1 Title

NDC12 Readiness Planning Guide

6.6.5.2 Subtitle

Industry Planning Guidelines, Project Phases, and Planning Approaches for NDC12 Implementation

6.6.5.3 Topics

- NDC12
- 12-digit National Drug Code
- FDA Final Rule
- NDC12 Planning
- NDC12 Implementation
- Readiness Planning
- Healthcare Interoperability
- Pharmaceutical Labeling
- Project Planning
- Trading Partner Readiness

6.6.5.4 Audience

Manufacturers, Repackagers, Distributors, Pharmacies, Providers, Payers, Software Vendors, Healthcare IT Leaders, Regulatory Affairs, Program Managers.

6.7 About the Author

Herb Wong has spent more than 30 years helping organizations solve complex technology and supply chain challenges. During that time, he has led customer implementations, product strategy, and industry initiatives involving pharmaceutical traceability, DSCSA, GS1 standards, Digital Link, and healthcare interoperability.

As the healthcare industry begins its transition to the 12-digit National Drug Code (NDC12), Herb is working with industry stakeholders to help organizations understand the operational impact of the change and develop practical implementation strategies. His perspective combines decades of implementation experience with lessons learned from industry workshops, standards organizations, and discussions across the healthcare ecosystem.

The goal of NDC12.com is simple: provide practical guidance, planning tools, and educational resources that help organizations prepare for NDC12 with confidence.

Additional articles, planning resources, and the free NDC12 Readiness Planning Tool are available at the website below.

Website: https://NDC12.com

LinkedIn: https://linkedin.com/in/herbwong