THE NDC-12 CROSS-INDUSTRY PILOT

IMPLICATIONS AND FINDINGS FOR THE PHYSICAL SUPPLY CHAIN

BUILDING THE BRIDGE TO NDC-12 TOGETHER

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Table of Contents

NDC-12 PHASE “1” PILOT	3
PILOT PURPOSE	3
TRACK 1	4
TRACK 2	4
INCREASED CLARITY TOWARDS THE NDC-12 RULE	5
NDC-12 PHASE "1" PILOT FINDINGS	6
EXTENDING THE PILOT SCOPE	6
WHAT ARE THE RISKS?	7
HOW CAN THE PHYSICAL SUPPLY CHAIN OPERATE AROUND THE TRANSITION	8
ARTWORK AND LABELING	8
ELECTRONIC DATA EXCHANGE	9
CONCLUSION	10
THANK YOU TO OUR PARTICIPANTS	11
APPENDIX	12
ABBREVIATION TABLE	12
RECTANGULAR BARCODE CAPACITY EXAMPLES	15
NNIT SUPPLY CHAIN SERVICES	16

THE NDC-12 INDUSTRY PILOT: PHASE 1

PILOT PURPOSE

Facing growing limitations in the availability of labeler codes within the current National Drug Code (NDC) framework, the FDA has published the draft rule on July 22nd 2022, and the finalized rule on March 5th, 2026. The purpose of the rule is to provide a transformation framework to standardize to a single 12-digit NDC format — a necessary evolution to sustain long-term scalability and enhance consistency in product identification. As such, NNIT initiated the overall pilot program in the fall of 2025 with the participation of many leading industry participants. The primary intent is to "educate and invigorate" the industry to prepare for the upcoming transformation. By bringing awareness of the 6-digit labeler codes and the NDC-12 Rule adoption approach, we hope to kickstart the industry into acting now by:

"Building a Bridge to NDC-12 Together".

While the rule is driven by regulatory necessity, its impact extends well beyond regulatory systems. The NDC is a foundational data element across operational, commercial, financial, and compliance workflows and clearly crosses company boundaries. As a result, the transformation to NDC-12 represents a cross-industry change and challenge that will require coordinated planning, business process alignment, and system updates across the pharmaceutical ecosystem to avoid significant disruption.

Every organization should start immediately with assessments of their processes, systems, trading partners, and vendors.

Many decisions, priorities, and dependencies will need to be determined as part of this transformation. Each decision will affect processes differently, creating a spiderweb of project planning that will need to be considered carefully before implementation.

There is urgency for the industry to align on directional usage and / or standards towards both the artwork changes and the master data representation for the NDC-12 with the NDC-10.

The industry is reliant on these two key decisions to be able to know the capabilities needed for the NDC-12 transformation. Trading partners, service providers, and other supply chain participants cannot fully define the scope of their programs until these needed capabilities are defined.

This paper is intended to help organizations in identifying impacts and complexities in effort to understand the magnitude of the transformation.

PHASE “1” OBJECTIVES

Pilot Phase “1” was initiated to provide a continuation of the work done in Phase “0”. The pilot was utilized as a platform to increase industry education and further the impact analysis to aid supply chain partners, regulatory bodies, and standards organizations to evolve the thinking towards the magnitude and complexity of the transformation from a 10-digit to a 12-digit NDC. Findings, ideas, and recommendations will be delivered to the participants and industry groups through the Phase “1” educational webinar, the published white paper, and an executive summary. The Phase “1” Pilot will focus on creating impact awareness so that organizations can begin their own assessments and understand the dependencies before implementation. To reach these objectives, this pilot phase was divided into two tracks to create discussion and analysis of specific scope and topics.

TRACK 1

Financial and Commercial Channel:
While Pilot Phase “0” concentrated on analysis of the physical supply chain, it was noted that much of the complexity moving forward would reside in the financial and commercial channels. Phase “1” Track 1 was dedicated to filling that analysis void. Using the familiar analysis approach of “Identify, Analyze, Strategize”, participants delved into the impacted processes with the goal of determining high-risk areas and decisions that face the industry. Three main topics were addressed during the virtual and face-to-face workshops:

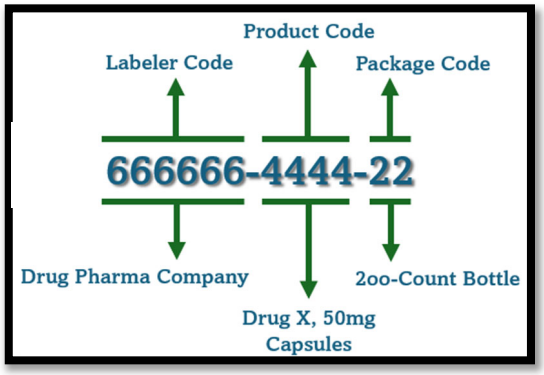
Topic 1: Foundational
Topic 2: Commercial Execution & Transaction Processing
Topic 3: Financial Settlement & Regulatory Overlay

TRACK 2

Physical Supply Chain Simulation:
The Phase “0” pilot defined high-level functional areas of the pharmaceutical supply chain before breaking down the business processes nested within each area. With a good foundation set, Phase “1” sought to explore the sub-processes within each of the functional groups and identify risks at each step; what could go wrong when there are two versions of a label in the warehouse, for example. The pilot timeline scope was set to the time before, during, and after the transition period, which offers unique challenges and potential confusion that will require early planning and mitigations to strive for a smooth transformation, avoiding product shortages and high error rates requiring manual workarounds. Simulations represented Artwork Changes, a (serialized) Manufacturing Line Solution, and an End-to-End workflow. Through the effort of designing and executing these simulations, pilot participants were able to sort out some of the highest pain-points that face the industry, as well as pressure-test real-world solutions prior to planning their own transformations.

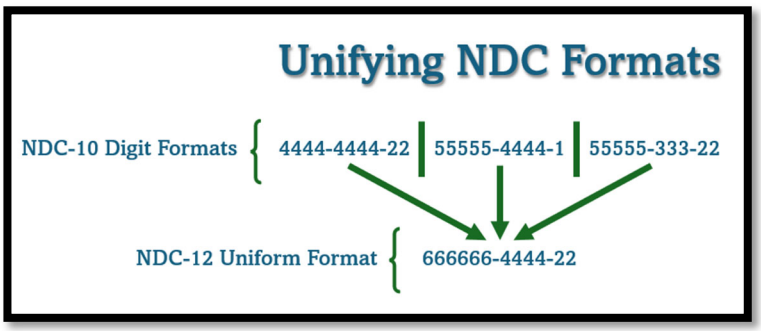
INCREASED CLARITY TOWARDS THE NDC-12 RULE

On July 25th, 2022, the FDA released the proposed rule titled: "Revising the National Drug Code Format and Drug Label Barcode Requirements", which was later finalized on March 5th, 2026. (Note: For further detail of the rule, please refer to our Pilot Phase "0" White Paper.)



The intent of this rule is to minimize the expected impacts of when the FDA runs out of 5-digit labeler codes by going to a uniform NDC-12 format. Even with all the risks and pain-points that exist around the co-existence period, the end goal of the transition, as stated by the FDA, is increased patient safety, operational efficiency and potentially long-term cost savings.
When this rule was finalized, the FDA estimated that they would run out of 5-digit labeler codes within 10-15 years. The most recent feedback from the FDA confirmed that there are about 10,000 5-digit labeler codes left, and the consumption rate is approximately 1000 labeler codes per year. The current timeline does not consider factors like a pandemic, where 7000 labeler codes were consumed in a single year!
Pre-existing regulations state that the FDA will begin to issue 6-digit labeler codes once they run out of 5-digit labeler codes, however, it does not set a specific timeframe to do so, nor does it provide a standardized format to do so.

The new rule offers a means to reduce some of this complexity and potential confusion that will be brought into the supply chain by the introduction of the 6-digit labeler code by switching to a new, uniform, 12-digit format for the NDC. This will include the new 6-digit labeler code, a 4-digit product code, and a 2-digit package code. Switching to a single form of the NDC and no longer allowing the use of the 10-digit NDC, will hopefully eliminate the need to constantly convert NDCs between their 10-digit NDC and 11-digit formats. This will ultimately depend on whether HIPAA aligns their standards with the new 12-digit NDC. The rule also states the FDA's intention to amend the current regulation to allow for the use of linear or non-linear barcodes that will support these label changes. A couple key topics that have been discussed either directly as part of Phase "1", or indirectly via different industry discussions of the rule, are as follows:



FDA amendment to the linear barcode regulation:
The UPC-A barcode has been the traditional data capture method for retail. Inherently for US pharma , it also (in most cases) serves as the means of housing the 10-digit NDC code. While the UPC-A barcode could possibly remain for some products (i.e.: certain OTC), standing alone it will no longer be a suitable means for complying with the FDA's linear barcode rule (21 CFR 201.25) due to the fact that the new 12-digit NDC exceeds the capacity of the UPC-A barcode.

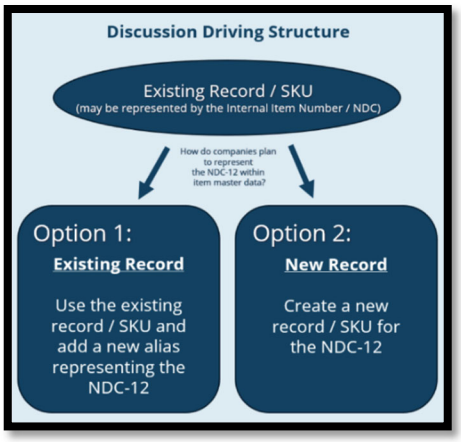
Through responses to industry comments, the FDA has identified a need to allow either a different linear barcode (i.e.: GS1-128, GS1 DataBar Stacked Expanded) or shift towards using a non-linear barcode like the GS1 DataMatrix (square or rectangular). The impact of changing to a new barcode is being assessed at an industry level and standards organizations plan to align on the best barcodes to use moving forward.

Introduction to Interstate Commerce at the Effective Date:
As part of the final rule, the FDA clarified that NDC-10 labeled product "introduced or delivered for introduction into interstate commerce" before or after the effective date would be treated differently at the end of the Transition Period. While the FDA rule does not explicitly define "introduced or delivered for introduction into interstate commerce", Industry has generally interpreted this statement to mean a sale / transaction / change of ownership to an authorized trading partner. With that said, the FDA confirmed that NDC-10 labeled product "introduced or delivered for introduction into interstate commerce" prior to the effective date can live out the life of its expiration within the supply chain, even if this extends beyond the end of the Transition Period. NDC-10 labeled product "introduced or delivered for introduction into interstate commerce" after the effective date must be removed from the supply chain at the end of the Transition Period.

NDC-12 Phase "1" Pilot Findings

EXTENDING THE PILOT SCOPE

Financial, Commercial Channel:
After concluding Phase "0", our teams' efforts were directed to expand the scope into the nebulous realm of the commercial and financial processes that certainly will be impacted by the upcoming transformation of current NDCs to the 6-4-2 format. Workshops were conducted to analyze the three topic areas (foundational, transactional, settlement / regulatory) for impacted processes individually, but we found that the same themes and risks tended to apply to each of the processes. Although many processes were studied and analyzed, the groups conversations would often come back to the foundational topic of Master Data. Why? Because how you decide to manage, update, and map your master data has cascading effects on every other decision, process, and affects how you approach your change management. To understand these outcomes, we initially broke down the updates into two options;



Option 1: Use the same record and add an attribute or alias field
Option 2: Create a new record representing the NDC-12 labeled product

As the pilot progressed and workshops revealed points of concern, participants weighed in on pros and cons of each option, noting that there is no specific best option. Different scenarios may lead to a different option. The best option for a manufacturer may be less desirable for, say, distribution. Even within a given company, one option may be more advantageous for one area vs. other areas (e.g. manufacturing prefers two SKUs / commercial prefers one SKU). Considering variables such as the time industry has before the effective date and when one can actually

submit changes, a blend of option 1 and 2 became a realistic 3rd approach. System limitations may dictate that there can only be one record where other software or business rules allow the 'ingredients of the recipe' to be substituted.

Note: This decision is not binary. Companies will likely choose a hybrid approach depending on individual product needs and / or their business processes / systems limitations. Great care should be taken, however, to ensure data transactions with trading partners are synchronous.

Beyond the foundational topics, we spent time looking into the financial and commercial processes that affect the industry as a whole. Whether your specific processes are managed manually, automatically, insourced or outsourced, the implications of errors will impact your financial and commercial bottom lines. The opportunity for data mismatches, errors resulting from insufficient data mapping, and product shortages due to miscommunications or improper forecasting is high as we approach these industry wide changes. Financial processes affect everything in a business, so when discussing the impacts to the financial channel, one must consider the matrix of other affected processes.

WHAT ARE THE RISKS?

The NDC-12 transition carries risks across the supply chain. Improperly mapped NDC formats can produce inaccurate inventory reports, corrupting the historical and financial data that drives forecasting and procurement, and potentially causing shortages or overages. An unexpected demand spike could exhaust 10-digit NDC stock before the effective date, leaving manufacturers unable to ship 12-digit labeled product as a stopgap. Patient safety is at stake if inconsistent planning / adoption by trading partners reduces supply visibility, delays fulfillment, or misdirects product, leaving patients waiting on prescriptions.

How about the effects on Controlled Substance Ordering Systems (CSOS)? The CSOS application will need to be updated to be capable of supporting the NDC-12 and managing the relationship to its predecessor NDC-10 format. Standard EDI transactions will need to be updated, similarly to the non-controlled process. Additionally, the manual 222 form that is still used by many supply chain partners today will need to be updated to support the NDC-12. Regulatory and Compliance Reporting systems and programs such as Automation of Reports and Consolidated Orders System (ARCOS) and Risk Evaluation and Mitigation Strategy (REMS), Suspicious Order Monitoring Systems (SOMS), Prescription Drug Monitoring Programs (PDMP), among others, face the same data mapping and synchronization challenges as many other systems already talked about in this pilot. Mapping, again, will be very important with systems like Medicare / Medicaid which are required to submit priced-based calculations. Companies typically use 3rd party vendors to make submissions to Medicare / Medicaid.

Many of the financial and commercial processes have common themes within the physical supply chain. There is clear overlap between the two tracks. Within the next section we will discuss the continued investigation into the physical supply chain.

HOW CAN THE PHYSICAL SUPPLY CHAIN OPERATE AROUND THE TRANSITION

Our primary goal of Track 2 of this Pilot was to envision how the physical supply chain might look prior, during and after the transition period. Not only do we want to consider the physical changes to the labels and packaging lines but also consider how supporting data and documentation is affected during this co-existence timeframe. Unsurprisingly, the topic of Master Data almost immediately crept its way into Track 2; with a decision on how physical attributes of the same product are distinguishable in the aforementioned periods.



Track 2 of the Phase "1" Pilot centered its attention to the problems and potential management that the industry as a whole will face during the co-existence period. We've approached this time period as not only the FDA defined "transition period", but also an undefined amount of time prior to and preceding the "transition period". In order for companies to prepare efficiently, data will certainly be set up, tested and transacted prior to the "effective date". On the flip side, NDC-10 product and data transaction will linger in the supply chain for years to come after the "transition period" concludes. NDC-10 product introduced into the supply chain prior to the effective date will remain legitimate after the transition period ends. Some products have expiration dates of up to 10 years, meaning the co-existence period will last longer than you might have originally expected.

ARTWORK AND LABELING

Approach:

As the pilot group was looking through the entire supply chain process, GS1, as one of the standards organizations for pharmaceutical barcoding, initiated their weekly NDC format meetings. This workgroup was developed to discuss the potential barcode replacements available to the industry when the UPC-A is no longer viable for the NDC — as well as initiating the development of the NDC guidance document for industry. Considerations were made to find options that would still provide a linear format, as well as formats that could replace barcodes on small space-constrained labels. Over several sessions, we studied the proposed barcode replacements to assess the practicality of using each under different scenarios.

Barcode Type	Image	Character Capacity (numeric)	Physical Size (GTIN + NDC-12 + DSCSA encoded)	Current Applications
GS1 DataMatrix (square)		3,116	Min – 0.39" x 0.39" Max – 1.0" x 1.0"	Healthcare items
GS1 DataMatrix (rectangular)		98	Min – 0.72" x 0.24" Max – 1.84" x 0.61"	N/A
GS1-128		48	N/A	SSCC on cases and pallets
GS1 DataBar Expanded Stacked		74	Min – 1.75" x 0.88" Max – 4.0" x 1.98"	Expiration dates on fresh foods

ELECTRONIC DATA EXCHANGE

The pharmaceutical supply chain is no stranger to the exchange of electronic data. Although we understand there are many file formats that are common to the industry such as ERP solution platforms, structured submission templates or segmented B2B exchange envelopes. The pilot program focused its discussions on EPCIS for product traceability events (referencing GS1 Implementation Guidelines) and EDI (leveraging HDA contributions) for structured commercial transactions. The NDC-12 transition is often compared to Y2K, since many companies still rely on older electronic data exchange standards that were not built to represent the new identifier format. Although those older formats can technically carry the longer number, they lack the qualifiers needed to identify it correctly. A newer standard is expected to offer more flexibility in supporting the different identifier formats, and organizations will be strongly encouraged to upgrade. Most transaction types within the newer standard already have this capability, but a few exceptions remain, and it is still unclear whether other transaction categories, such as those used for warehouse management, will receive similar updates. EPCIS messages present their own set of challenges for the NDC-12 transition. Product identification within a message is anchored by the GTIN, which will not need to change, but the way the National Drug Code is represented does need to be updated. Current guidance specifies one format for carrying the NDC, though inconsistent practices, such as the use of dashes, remain common. A newer version of the implementation guide updates how the code is identified and will allow multiple formats to be represented. Several open questions remain for the industry after the effective date: which format should be used, whether flexibility should be allowed for more than one, how mixed shipments should be handled, and whether electronic data should reflect the product's regulatory listing or exactly what is physically shipped. Because existing practices may not perfectly match the physical product, the industry will need to work with the standards body to reach a consensus.

To some degree of certainty, all organizations that use electronic data exchange will need to align or update systems and processes to allow for capabilities to include the updated 12-digit NDC. It is important to stay abreast of current and future industry guidance regarding electronic data exchange.

CONCLUSION

Assessments

Organizations frequently discover that no single department has complete visibility into how the NDC is used across the enterprise. Regulatory understands product registration. Packaging understands artwork. Manufacturing understands production. Commercial understands pricing and contracts. Finance understands settlement and reporting. IT understands the supporting technology landscape.

A structured assessment creates the opportunity to connect those perspectives, identify gaps, and build a shared understanding before remediation activities begin. In many respects, that organizational alignment becomes just as valuable as the technical findings themselves.
The organizations making the greatest progress today are not necessarily the ones with the largest teams or the most detailed implementation plans. They are the ones investing the time to understand their current state before deciding how to change it.

An effective NDC-12 assessment looks beyond individual applications. It examines the physical product, the business processes that support it, the systems and service partners that enable those processes, the data exchanged between partners, and the governance needed to coordinate change across the enterprise. Only with that complete picture can organizations build realistic budgets, practical roadmaps, and achievable implementation strategies.

Early Action

Decisions for artwork and NDC-12 representation are key for the industry to be able to move forward. This needs to be addressed quickly by the industry for directional usage and / or standards. This will allow manufacturers to complete the definition of their program in terms of artwork and master data. Only then will the true scope of the transformation be known by trading partners, service providers, and the general industry. Early awareness, planning and preparation is the key for the industry and its participants. Now is the time to reach out to vendors and trading partners to map out the dependencies of your transition program. While there are still a few uncertainties remaining, future guidance and Q&A documents are planned from the FDA.

Technology stacks can be upgraded with backwards compatibility and flexibility built in to ease the co-existence period. Large artwork and barcode changes can take place anytime in the next seven years to simplify the NDC-12 change on or after the effective date. Data governance programs can get the traction they've always needed to clean and standardize data now, removing predictable speedbumps in the future. Organizations can use simulation techniques, like those described in this paper, to begin implementing these changes. It's a long on-ramp to the effective date that will quickly become a traffic jam if organizations choose to delay. No one should assume that the FDA will delay this initiative as they have in the past; there is a finite timeline until the five-digit labeler code runs out. It has been predicted to be 10 years' worth but is likely an unpredictable amount of time.

THANK YOU TO OUR PARTICIPANTS

Pilot Phase “1” would not have been possible without the support and contributions of our participants. Many people representing different functional roles attended seemingly endless workshops to evolve our thinking toward the problems that lay ahead. We would like to acknowledge each company that dedicated time and resources to this incredibly important topic:



APPENDIX

ABBREVIATION TABLE

Abbreviation	Description
3PL	Third Party Logistics
ANSI	American National Standards Institute
AP	Accounts Payable
API	Active Pharmaceutical Ingredients
AR	Accounts Receivable
ARCOS	Automation of Reports and Consolidated Orders System
B2B	Business to Business
BCP	Business Continuity Plan
BLA	Biologics License Application
CBE	Changes Being Effected
CFR	Code of Federal Regulations
CMO	Contract Manufacturing Organization
CMS	Centers for Medicare & Medicaid
CPO	Contract Packaging Organization
CSOS	Controlled Substances Ordering System
DC	Distribution Center
DEA	Drug Enforcement Administration
DSCSA	Drug Supply Chain Security Act
EDI	Electronic Data Interchange
EPCIS	Electronic Product Code Information Service
ERP	Enterprise Resource Planning
FDA	Food and Drug Administration
FD&C	Federal Food, Drug, and Cosmetic Act
GS1	Global Standards One
GTIN	Global Trade Item Number
GXP	Good x Practice
HCT/P	Human Cells, Tissues, and Cellular and Tissue-Based Products
HDA	Healthcare Distribution Alliance
HIBCC	Health Industry Business Communications Council
HIPAA	Health Insurance Portability and Accountability Act
HRI	Human Readable Information

Abbreviation	Description
MAH	Marketing Authorization Holder
MES	Manufacturing Execution System
ICD	International Classification of Diseases
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
IT	Information Technology
MD	Master Data
MRP	Materials Requirement Planning
NABP	National Association of Boards of Pharmacy
NCPDP	National Council for Prescription Drug Programs
NDA	New Drug Application
NDC	National Drug Code
NHRN	National Healthcare Reimbursement Number
NLM	National Library of Medicine
O2C	Order to Cash
OTC	Over the Counter
PAS	Prior Approval Supplement
PDMP	Prescription Drug Monitoring Programs
PI	Product Identifier
POS	Point of Sale
QMS	Quality Management System
RA	Regulatory Affairs
RC	Regulatory Compliance
REMS	Risk Evaluation and Mitigation Strategies
RMA	Return Material Authorization
SC	Supply Chain
SCADA	Supervisory Control and Data Acquisition
SGTIN	Serialized Global Trade Identification Number
SKU	Stock Keeping Unit
SN	Serial Number
SOMS	Suspicious Order Monitoring Systems
SOP	Standard Operating Procedure
SPL	Structured Product Labeling
SSCC	Serialized Shipping Container Code

Abbreviation	Description
T2	Transaction Information/Transaction History
TMS	Transport Management Systems
VRS	Verification Router Service
WCS	Warehouse Control System
WDD	Wholesale Drug Distributor

RECTANGULAR BARCODE CAPACITY EXAMPLES – TARGET SIZE (LEFT) & MIN SIZE (RIGHT)

AI(01) GTIN – n2+n14 | AI(10) Lot – n2+x...20 | AI(17) Exp – n2+n6 | AI(21) Sn – n2+x...20 | AI(715) NHRN – n2+x...20

Example 1

A 'typical' representation of current 4-element GS-1 DataMatrix PI ***with*** the addition of AI-715 shows a character count of 72 when using all Numeric serial number (n...12) and an AlphaNumeric Lot code (x...7)

72



(01) 0 0000123 00001 7
(21) 123456789012
(17) 040104
(10) ABC1234
(715) 666666444422



(01) 0 0000123 00001 7
(21) 123456789012
(17) 040104
(10) ABC1234
(715) 666666444422

Example 2

The 5- element DataMatrix has been updated to maximize the Numeric serial number (n...20) and the Lot is also maximized (n...20) to show a character count of 93 when using ***all*** Numeric characters.

93



(01) 0 0000123 00001 7
(21) 12345678901234567890
(17) 040104
(10) 12345678901234567890
(715) 666666444422



(01) 0 0000123 00001 7
(21) 12345678901234567890
(17) 040104
(10) 12345678901234567890
(715) 666666444422

Example 3

The 5- element DataMatrix has been updated to maximize the Alpha serial number (x...20) and the Lot is updated to a 10-digit Alpha (x...10) to show a character count of 83

83



(01) 0 0000123 00001 7
(21) ABCDEFGHILKLMNOPQRST
(17) 040104
(10) ABCDEFGHIJ
(715) 666666444422



(01) 0 0000123 00001 7
(21) ABCDEFGHILKLMNOPQRST
(17) 040104
(10) ABCDEFGHIJ
(715) 666666444422

Example 4

The 5- element DataMatrix remains maximized for the Alpha serial number (x...20) and the Lot is updated to an 11-digit Alpha (x...11) to show a character count of 84 and the ***forcing*** of the larger capacity Square DataMatrix code

84



(01) 0 0000123 00001 7
(21) ABCDEFGHILKLMNOPQRST
(17) 040104
(10) ABCDEFGHIJK
(715) 666666444422



(01) 0 0000123 00001 7
(21) ABCDEFGHILKLMNOPQRST
(17) 040104
(10) ABCDEFGHIJK
(715) 666666444422

NNIT SUPPLY CHAIN SERVICES

NNIT Supply Chain Services safeguards product integrity, prevents counterfeiting and ensures patient safety, compliance and deliverability.



Our experts work extensively across the therapy development life cycle to deliver optimal end-to-end solutions. Our Supply Chain services add innovation to compliance while delivering value at every stage of your operations. We combine expertise with optimum enabling technologies to drive value.

Life sciences and pharmaceutical manufacturers, distributors, and third-party logistics providers face the dual challenge of combating counterfeiting and safeguarding product integrity. Ensuring patient safety demands precise serialization and full traceability throughout the supply chain - from manufacturing to product delivery and distribution. Achieving this level of transparency requires comprehensive visibility across every operational aspect.

To learn more about the next phase of the NDC-12 Cross-Industry Pilot, contact us at nnitcontact@nnit.com

nnit

We make a mark

About NNIT

We are an international digital consultancy specializing in life sciences and the public sector. Our team of leading industry subject-matter experts and technology consultants help you empower those who change lives – and make a mark.

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