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Centers for Disease Control and Prevention

Two-Dimensional (2D) Vaccine Barcoding Manufacturers Forum Report

"Reviewed November 2015"

The 2D Vaccine Barcoding Pilot is funded by the Centers for Disease Control and Prevention (CDC) and managed under contract by Deloitte Consulting, LLP (Deloitte). A two-year contract to design and implement the barcoding pilot was awarded to **Deloitte** in September 2011.

November 2014

Version Control

Version	Date	Changes
0.0	2/29/12	Initial Draft

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1.0 Executive Summary

The 2D Vaccine Barcoding Manufacturers Forum was conducted January 26, 2012 at the Tom Harkin Global Communications Center on the Centers for Disease Control and Prevention (CDC) Roybal Campus located at 1600 Clifton Road, Atlanta Georgia. Over 60 industry stakeholders attended in person. Attendees included 26 representatives from 10 vaccine manufacturing companies, representing functions of packaging, distribution, policy, regulatory affairs, technical services, customer service and new products. In addition to the manufacturers, the forum was attended by representatives of retail pharmacy supply chain participants, standards bodies, and trade associations such as GS1 and BIO. Regulatory and global agencies including World Health Organization (WHO), the Food and Drug Administration (FDA), and CDC participated in the event, providing a rare opportunity for the industry and regulators to connect and discuss the changing requirements and standards for vaccines.

The forum was structured to provide information on several key topics including the CDC's 2D Vaccine Barcoding Pilot, current FDA guidance on 2D Vaccine Barcoding, overall industry progress on 2D barcoding, and standards development in the 2D barcoding space. Opening remarks were made by Dr. Anne Schuchat, CDC—Assistant Surgeon General, United States Public Health Service (USPHS) Director, National Center for Immunization and Respiratory Diseases, who emphasized the importance of the pilot's goals of improving information flow and accuracy, and patient safety.

An overview of CDC's Vaccine Barcode Pilot project was given by Erin Kennedy, DVM, MPH, of the CDC. Regulatory guidance for manufacturers was addressed by Captain Vada Perkins, FDA, followed by a provider perspective given by Dr. Edward Zissman, MD, FAAP who represented the American Academy of Pediatrics (AAP). An overview of the Vaccine Barcoding Report, which was funded by the CDC was given by Alan O'Connor of Research Triangle Institute International (RTI), followed by a final presentation by John Roberts of GS1, the global standards organization focusing on the need for adopting data standards to drive the benefits of 2D vaccine barcoding.

Following the speaker presentations, working sessions were held with forum attendees to discuss the benefits and impacts of 2D vaccine barcoding. Topics for the breakout working sessions were standards, user adoption and time and cost. Below are highlights from those working sessions.

- Manufacturers recognize the value of 2D barcoding to the provider community, but struggle with implementing in a cost effective way.
- There is confusion and concern about regulatory requirements that is slowing rapid adoption. The FDA is willing to address this and work with the manufacturers to resolve the uncertainty.
- There will be a period of time where all vaccine products will carry both linear and 2D barcodes, until there is sufficient uptake of 2D symbology by providers and migration away from linear barcodes.
- GS1 is the standard that manufacturers have adopted for use in the supply chain.
- Forum participants welcome the opportunity to work collaboratively with agencies and peers on defining the benefits and seeking ways to solve issues and enhance patient safety.
- There is a need for alignment between vaccine manufacturers and vaccine end-users, or immunizers. Manufacturers cannot drive the adoption of 2D barcoding alone.

2.0 Background

In September 2011, the CDC initiated a pilot designed to evaluate how 2D vaccine barcodes may affect the quality, accuracy and timeliness of the exchange of immunization-related information between electronic immunization provider recording systems and grantee Immunization Information Systems (IIS), among other systems. A two-year contract to design and implement the pilot was awarded to Deloitte Consulting.

By moving from a linear to a 2D barcode, vaccine manufacturers can more efficiently provide data about vaccine products. It is anticipated that by scanning a 2D barcode into an electronic provider immunization recording system, immunizers can easily and accurately capture data with a single scan.

As part of the pilot, a 2D Vaccine Barcoding Manufacturers Forum was organized to bring together vaccine manufacturer, regulatory and standards stakeholders to discuss the opportunities, challenges and next steps for implementing 2D barcoding on vaccine products. A full list of forum sponsors and attendees are displayed in Appendix B and C.

3.0 Forum Goals and Objectives

The goals and objectives of the forum were to engage the vaccine manufacturing community in the discussion of the benefits, impacts and challenges of implementing 2D barcoding, to understand the regulations and standards landscape in more detail, and to explore the options and considerations for moving the industry forward toward the implementation of 2D barcoding of vaccine products.

4.0 Forum Agenda

The agenda was designed to bring together key groups involved in the creation and adoption of 2D Vaccine Barcoding. The agenda included presentations about the pilot from CDC representatives as well as other speakers who discussed key issues in vaccine barcoding. The FDA was selected to provide details on the regulatory process for 2D vaccine barcoding, which was of prime interest to the manufacturer attendees. The AAP, the Pilot's primary industry group sponsor, provided a key voice into immunizer (specifically pediatric) adoption considerations. RTI was selected to present as they have conducted with CDC support the primary research to date on vaccine barcoding and could provide insight on the potential benefits to be achieved by adopting 2D barcoding. GS1 provided insights on the latest standards around barcoding to help the manufacturers understand the likely standards that will be used as part of 2D Vaccine Barcoding.

The agenda also included breakout "working sessions" to encourage dialogue between attendees to highlight perceptions and issues around 2D vaccine barcoding standards, user adoption, and time and cost commitment.

Time	Description	Presenter
11:00 – 11:05	Welcome Opening Remarks	*Bonni Kirkwood* Deloitte—PM 2D Vaccine Barcode Pilot Project *Anne Schuchat, MD* CDC—Assistant Surgeon General (USPHS) Director, National Center for Immunization and Respiratory Diseases
11:05 – 11:10	Forum Purpose and Objectives Antitrust Announcement	*Bonni Kirkwood* *Ken Gerlach, MPH, CTR* CDC— NCIRD/Immunization Services Division, Health Scientist
11:10 – 11:30	Overview of 2D Vaccine Barcoding Pilot	*Erin Kennedy, DVM, MPH* CDC— NCIRD/Immunization Services Division, Medical Officer
11:30 – 12:00	Overview and Guidance on Vaccine 2D Barcoding	*Vada Perkins, BSN, MSc, RN* FDA—Chief, Business Operations Staff
12:00 – 12:30	Lunch	
12:30 – 1:15	Industry Goals and Progress for Vaccine Barcoding – A Perspective from the AAP	*Edward Zissman, MD, FAAP* AAP
1:15 – 2:00	Overview of Vaccine Bar Coding Report	*Alan O'Connor* RTI—Senior Economist
2:00 – 2:15	Break	
2:15 – 3:00	Emerging Standards for Vaccine Barcoding – GS1 Overview	*John Roberts* GS1—Director, Healthcare
3:00 – 3:05	Overview of Working Sessions	*Bonni Kirkwood*
3:05 - 4:15	Benefit/Impact Working Sessions	3 sessions with facilitators
4:15 – 4:55	Working Session Readouts	*Bonni Kirkwood*
4:55 – 5:00	Close Forum	*Warren Williams, MPH* CDC— NCIRD/Immunization Services Division, Informatics Team Lead, Immunization Information Systems Support Branch

Table 1 – Manufacturer Forum Agenda

5.0 Speaker Presentations

The slides used for each speaker presentation can be found in Appendix A.

Welcome – Dr. Anne Schuchat, MD CDC – Assistant Surgeon General (USPHS) and Director, National Center for Immunization and Respiratory Diseases

Dr. Schuchat's opening remarks placed emphasis on the importance of the pilot. She described a recent experience in rural Africa where, with a scan of a barcode, a nurse could present information around the therapy that a patient was receiving. Dr. Schuchat stated this experience should be motivation for improving our efforts in the United States. Dr. Schuchat provided an overview of the vaccine supply chain and the use of the CDC vaccine ordering system (VTrckS) in the process. She also touched on the impact of 2D barcoding on managing shortages, recalls and safety tracking, decision support and meaningful use.

Overview of 2D Vaccine Barcoding Pilot - Dr. Erin Kennedy

Dr. Kennedy provided an overview of the 2D Vaccine Barcoding Pilot Project, including a description of the progress of 2D vaccine barcoding efforts since 2004.

The key points of Dr. Kennedy's presentation included:

- Definition of linear vs. 2D barcoding indicating that linear barcodes contain the NDC code only and that 2D barcodes can capture additional information like expiration date and lot number
- Potential public health benefits of the 2D Vaccine Barcoding Pilot include improved accuracy of patient health records, consistency in information captured in IIS and VAERS reports, increased ability to identify safety concerns and a potential reduction in administration errors
- The 2D Vaccine Barcoding Pilot's objectives are to examine the challenges of implementing 2D barcodes on vaccines and to evaluate the use of 2D barcodes via assessing data completeness, user experience, and process impacts, and to document best practices and lessons learned
- The Pilot's timeline begins with manufacturer, grantee, and immunizer enrollment and provisioning through mid-2012, continues with immunization tracking through April 2013, with a final report following in June 2013
- Current Pilot progress includes two manufacturers enrolled, and 58 immunizers enrolled
- Barcoding will also be introduced on all Vaccine Information Statements (VIS) as part of the Pilot in order to achieve the benefits of increasing completeness of data elements, enhancing record keeping for providers, and promoting the use of barcoding technology
- The CDC has identified the GS1 Global Document Type Identifier (GDTI) to encode the VIS, added the GDTI barcode to all up to date VIS, and developed assistance documents for users

Questions & Answers*	
Question	**Answer**
[Zissman, AAP] Concern about nurses knowing which bar code to scan if 2D barcodes are on vaccine vials and VISs. There is no doubt that 2D	[Erin Kennedy, CDC] No, VIS codes are generic. We aim to offer sufficient training to educate nurses about which VIS code to scan.

barcodes will lead to accuracy improvements, but 'everything that can be messed up will be messed up'. Clear direction needs to be given to ensure providers understand the appropriate use of 2D barcode scanning. Adopting a change in workflow is huge. Workflow changes will be an issue for the practices. *Do the VIS codes contain vaccine specific barcodes?*	[Greg Anderson, Connexin] Nurses often print out barcode cheat sheets with multiple barcodes on one piece of paper. This makes their life easier to scan the barcodes, but causes concern about barcode accuracy.
[Melissa Melhame, Dynavax] What is the benefit of scanning the VIS?	[Erin Kennedy, CDC] To record and increase completeness of version date of the VIS.
[Zissman, AAP] Is there an interface to the Electronic Medical Records (EMR) developed as part of this pilot?	[Erin Kennedy, CDC] No interface.

*Questions and Answers captured in this report were not captured verbatim

Overview and Guidance on Vaccine 2D Barcoding – Captain Vada Perkins
Captain Perkins provided an overview on the FDA guidance for the use of 2D barcodes on vaccine products.

The key points of Captain Perkins' presentation included:

- Current barcoding requirements
    - Drugs approved on or after April 26, 2004, have 60 days from their approval date to comply with the bar code requirement (21 CFR 201.25)
    - All other drugs subject to the bar code requirement, including drugs with applications approved before April 26, 2004, must implement the requirements within 2 years of the effective date (i.e., no later than April 26, 2006) (21 CFR 201.25)
    - A drug manufactured on or after April 26, 2006, must bear a bar code
- 2D barcodes are to include National Drug Code (can support Global Trade Identification Number (GTIN)), Lot Number, Expiration Date
- Labeling submission for addition of a 2D barcode requires a Prior Approval Supplement (PAS) labeling submission
- Equipment that already has the capability for 2D barcode and will require validation for 2D barcode addition to the label. Manufacturers can contact Industry.Biologics@fda.hhs.gov for more information on manufacturing changes
- Manufacturers can request exemptions to the FDA/CBER review process for 2D barcode additions

Questions & Answers*	
Question	**Answer**
[Tim Marsh, Pfizer] Do we need linear and 2D?	[Vada Perkins, FDA].

Is an exemption possible?	There is a process to request an exemption to the linear barcode requirement. That being said, companies that have submitted 2D barcode submissions, to date, were "in addition to" requests.
[Craig Kemp, Merck] Just to confirm, you would like a PAS to be the filing mechanism to ensure consistency although at some point it may move to a Changes Being Effected in 30 Days (CBE-30)?	[Vada Perkins, FDA] Yes. Because there is a timing issue with the pilot, we will take quick action on those products to turn them around.
[Craig Kemp, Merck] Do we submit an exemption in addition to the PAS?	[Vada Perkins, FDA] An exemption is required only if you want to drop the linear.
[Greg Anderson, Connexin] There is not enough real estate to use both. Scanner will catch both far too easily--have to hold just right. It will be very difficult to teach nurses to scan one or the other code if both exist on the vial. There is interference between the two codes.	[Vada Perkins, FDA] We can only offer a mechanism to allow one or both--using the exemption processes. The exemption process applies only if a manufacturer wants to eliminate the linear when adding the 2D barcode. Linear in addition to the 2D will require a PAS labeling supplement
[Zissman, AAP] The AAP working group was told one or other?	[Vada Perkins, FDA] An exemption is only applicable if a request to remove the linear barcode is submitted.
[Novartis] Is an exemption required for each product?	[Vada Perkins, FDA] We will follow up on this.

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Industry Goals and Progress for Vaccine Barcoding - Perspective from AAP – Dr. Edward Zissman
Dr. Edward Zissman, representing the American Academy of Pediatrics, presented a historical and forward-looking overview of vaccine barcoding.

The key points of Dr. Zissman's presentation included:

- Pediatricians provide the majority of vaccinations in the U.S. leading the AAP to have a continued interest in barcoding on immunization vials and syringes
- Environmental changes such as an increase in the number of recommended childhood vaccines, an increase in vaccine data recording requirements, and an increase in the number of private practices using electronic systems have created greater need for improved vaccine tracking
- Guidance on how to track combination vaccines (vaccines with more than one vial that need to be combined for administration (e.g. Pentacel)) is needed
- Involvement and agreement of stakeholders is critical and AAP's ongoing task will be to educate stakeholders including vaccine administrators, software vendors, and immunization registries

Overview of Vaccine Bar Coding Report – Alan O'Connor
Alan O'Connor of RTI provided an overview of the Vaccine Bar Coding Project commissioned by the CDC in October of 2010.

The key points of Mr. O'Connor's presentation included:

- 2D barcodes are technically feasible and expected by stakeholders to enhance safety via automated product verification (right product, right patient) and improve accuracy and completeness of records
- Scanning 2D barcodes saves about 35 to 39 seconds per dose for documentation
- When made aware of estimated scanner, workflow redesign, and training costs,
    - 79.5% of pediatric practices said they would use the barcode or would use it if they had an electronic health record (EHR) system
    - 69.8% of family medicine practices agreed
- Estimated net economic benefits to Primary Care Providers , Local Health Departments, manufacturers, and some public-sector organizations
    - $326M to $349M, between 2011 and 2023
    - Net Present Value of $176M to $197M (7% discount rate)
    - Benefit-to-cost ratio of 2.7 to 2.8
    - Internal rate of return of 43% to 49%
- A mapping of GTIN to NDC to Manufacturers of Vaccines (MVX) and Vaccine Administered (CVX) codes is necessary for IT systems.

Questions & Answers*	
Question	**Answer**
[Unknown] Does the study focus on all 3 barcodes required. (Serialization etc.)?	[Alan O'Connor, RTI] The study looked at primary packaging only. Secondary packaging was not considered.
[Unknown] Guidelines good for Pediatricians but need to make sure that serialization is fully inclusive for track and trace.	
[Unknown] Cost? Does it include outside package too?	

[Zissman, AAP] Inventory control is very important. A large selling point is inventory control to reduce wastage. Reporting for fraud and abuse would be a huge selling point. *Note: [Zissman, AAP] The cost to the Pediatrician. Electronic Medical Records (EMR) upgrades and interfaces are not included.*	[Alan O'Connor, RTI] RTI looked into this: We engaged EHR vendors about requirements to incorporate scanners. The cost adoption was fairly low. The majority of vendors did not perceive incremental costs simply because of increased automation and barcoding. With respect to the comments about pediatrics and family practice markets, this was considered a key market driver for EHR vendors to push more. [Alan O'Connor, RTI] The cost was very small. [Alan O'Connor, RTI] Functionality could come as a push, as part of the yearly lease.
[Jay Crowley, FDA] Cautioned against parsing numbers. Parsing the NDC out of a GTIN is dangerous. It might work in the short term, but it will get us in trouble in the long term.	[Alan O'Connor, RTI] There are so many decision rules that need to be considered that a mapping is preferable. [Jay Crowley, FDA] Even mapping can cause trouble, we must be careful to acquire the information without parsing NDC to get it.
Note: [Zissman, AAP] Remember that billing uses a different form. Don't just think about medical records, also think about billing. If CDC takes ownership of the NDC mapping then they should consider other implications like billing and associated codes.	

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Emerging Standards for Vaccine Barcoding - GS1 Overview – John Roberts
John Roberts, Director of Healthcare for GS1 US provided an overview of the GS1 organization, GS1 standards and the nuances of barcoding using 2D symbology.

The key points of Mr. Roberts' presentation included:

- GS1 is a not-for-profit organization dedicated to the design and implementation of global standards to improve the efficiency and visibility of supply chains globally and across sectors
- GS1 standards focus on patient "rights": Right Patient (location) – Global Location Number (GLN), Right Drug/Device – GTIN, Right Dose – GTIN, Right Route – GTIN
- One data structure (GTIN) will be used to reference the item by all members of the supply chain (hospital & retail, manufacturer, distributor, Group Purchasing Organization (GPO)/Payer)
- There is "perfect standards storm" upcoming with the 2012 voluntary GTIN Sunrise, FDA Unique Device Identification, and California pedigree in 2015 amongst others, creating a strong case for standards adoption

- The 2012 GTIN Sunrise goal is to have GTINs assigned to all healthcare products, marked on all appropriate packaging levels, used in business transactions, scanned at point of delivery, used in product returns and recalls, and registered in a GDSN certified data pool
- GS1 offers education forums, webinars, toolkits, and case studies to help stakeholders get educated and increase adoption of GS1 standards

Questions & Answers*	
Question	**Answer**
[*Greg Anderson, Connexin] What is the likelihood that serials are going to show up at unit of use when it comes to vaccines?*	[John Roberts, GS1] I can't talk about vaccines, but I know that some manufacturers will send serials not to just California, but everywhere too.
[Alan O'Connor, RTI] GTIN + Serial number: what packaging level will we see a serialized GTIN?	[John Roberts, GS1] For Pedigree/California, it will go down to unit of use. I have seen both. Serialization is difficult due to real estate requirements. [Jay Crowley, CDC] Serial number: Just because it [a product] has a serial number, does not mean that it [the product] does not have a lot number. It is easier to recall a lot than 10,000 serial numbers. Packaging: it becomes a necessity to serialize higher levels of packages in my opinion (not speaking for FDA). In order to make this work for distribution and traceability, you need to put a serial number on the outer level of packaging. Use inference to determine serial levels of interior packages.
[Warren, CDC] Is there a requirement related to the order of the data within the barcode e.g. GTIN, Lot Number, and Expiration Date)?	[John Roberts, GS1] No GTIN has to be first and the rest come after. It is an art and it depends. There should be fixed size fields such as GTIN and expiration date up front.

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6.0 Working Sessions

Prior to the Manufacturers Forum, the registrants were asked to identify three opportunities or challenges that the implementation of 2D barcoding presented for the manufacturer and immunizer community. Three common themes emerged as the primary areas of interest:

- Standards – Both opportunities and challenges were identified with respect to standards. While the GS1 standard has emerged as the industry-accepted standard for barcoding, there were various levels of understanding and use of the standards and implementation timeframes.
- User Adoption – User Adoption was interpreted not only as adoption by the providers and customers of manufacturers, but also trading partners. While education and benefits will need to be a focus in the future, working through some of the current processes in place will take time.
- Cost and Time Commitment – It will take time for manufacturers to upgrade lines, redesign labels and purchase and reconfigure equipment in order to begin applying 2D barcodes to vaccine products. Ensuring use in the field is of utmost importance to help manufacturers invest in 2D barcoding.

The disproportionate number of submissions for these three areas made them the logical choice to be topics for the forum working sessions. Detailed responses received by attendees prior to the forum can be found in Appendix E. Appendix E also lists the additional areas of interest submitted by registrants.

The following section provides notes from each of the working sessions. Many of these notes are captured in bullet points or sentence fragments and are included to provide context and background for the opportunities and challenges summarized in Figure 2 in Appendix E. A full listing of working session groups and their associated attendees can be found in Appendix D.

Group 1 – Standards

The focus of Group 1 was to discuss the benefits and the challenges of adopting and implementing GS1 standards for vaccine products. Participants of this group can be found in Appendix D-Forum Working Session Groups. The questions asked of the group and the related discussion points are below:

1. **What are the benefits of switching from market-specific product and location identification numbers to global identifiers (specifically GTIN and GLN proposed by GS1)?**
    - Group members agreed that the use of global identifiers increases patient safety and outcomes.
    - The group also agreed that there should be no universal GTIN across the globe. The scope should be confined to U.S.; use the same packaging line but different label.
    - Cost savings from peel-off labels is minimal hence not a significant monetary incentive.
    - Supply chain integrity and management can improve with this program.

2. **What challenges revolve around switching to the common GS1 identifier types (e.g. NDC to GTIN)?**

- The scope of this conversation was significant because of the pending California Pedigree law. There was discussion of where the 2D barcode should be located. Should linear/2D or both be used?
- The group ruled serial number discussions to be out of scope because of volatile changes in secondary packaging.
- There is no forecast of use serial number on unit of use.
- The group agreed that the 2D barcode will be on the packaging in addition to the linear, so you will have both.

3. **What standards are currently used in the US in addition to or instead of GS1?**
   - The concern was that the industry is spending significant time discussing the GS1 standards – is there a potential that these standards could change?
   - The group felt that while Health Industry Business Communications Council (HIBCC) is another standard that is used, it is not likely that this would be where the industry will move.

4. **If all manufacturers and distribution channels do not harmonize on 2D barcode standards and timing for implementation, how will the industry be impacted? What are the benefits of being an early adopter?**
   - Pediatricians have a limited choice – they must use one of 3-4 companies – GlaxoSmithKline, Sanofi, or Pfizer. You will see an impact when all of these companies provide 2D barcodes.
   - Discussed the PAS process and the desire to try to move these through quickly, especially if a manufacturer is part of the Pilot program. This is assuming that the PAS does not bundle many other labeling changes in with the request to change to a 2D barcode, because those will need a full review.

5. **Do you believe there is a common understanding of the 2D barcoded fields and sequence to be encoded (GTIN/Expiration date/Lot number)? If not, what needs to be clarified?**
   - Yes. 2D on unit of use: encode the GTIN -> Exp. -> Lot (Agreement among group).

There was one item captured in the parking lot and it was suggested that working groups be formed to continue the discussion (see below paragraph). There are existing GS1 workgroups to address encoding standards. FDA suggested making packaging guidance more explicit and defining regulations and how to implement.

Combination vaccine products (vaccine with more than one vial that need to be combined for administration) were discussed and which of the lot numbers should be captured. No clear answer emerged. This topic could be part of a future focus group.

Group 2 - User Adoption

The focus of Group 2 was to discuss the benefits and the challenges of user adoption and how to educate the provider community to embrace 2D barcoding to enhance their processes. It was important to remember that users come in several types – the immunizer community is more than just administrators of vaccines. The questions asked of the group and the related discussion points are below:

1. **What demonstration of user benefits, if any, are manufacturers anticipating by adopting 2D barcoding?**
    - Different users will have different priorities (public vs. private)
    - Patient safety
    - Inventory control and management
    - Cost Savings (e.g. important for Pediatricians) – efficiencies
    - Clearly distinguish practices with high-low VFC product volume

2. **What are the major vehicles for manufacturers to enhance user adoption and create customer pull through the use of 2D barcodes? How will these communications be managed?**
    - Can manufacturers alone really drive adoption? Support from EMR vendors is needed to drive initial adoption because doctors can't implement if systems don't have a place for the barcode information to go.
    - There is a need to enlist a critical mass of manufacturers and users to jump start adoption. If it is too piecemeal or drawn out, it will be difficult to get any energy behind it.
    - There is a need to assist practices with variable levels of automation –some just have practice management systems, some have EMR. The approach we should take during the pilot should be to develop different guidance for each type and size of practice, including:
        - Target practices that already using EMRs
        - Develop guidance specific to each segment of practices
    - Do not overpromise – talk about what is coming, but be realistic to limit some from jumping ahead because they are very excited to do this.
    - Incentives for stakeholders will vary – there will need to be a different way to design incentives for each stakeholder group.
    - The pilot should assist with removing barriers to adoption like cost for EMR upgrades.

3. **What are the benefits and drawbacks of using linear and 2D barcodes on vaccines until the industry transitions to 2D? What is preventing the complete transition to 2D barcodes now?**
    - Drawbacks:
        - Confusion/errors on the part of those who administer vaccines which could lead to data capture errors. Since the goal is to get rid of errors, introducing barcodes may temporarily introduce errors during the learning period.

- Real estate concern is what goes on the label and where and making sure there is room for the barcode.
- There are unanswered questions right now about the general regulatory environment, how the waiver process will work, and how quickly manufacturers can move through the process.
- Logistical considerations that come from combination product – what do you scan/not scan? How do you ignore scans of things not intended to be scanned– multiple scanning?

- Benefits: There will be an easier transition for customers who might not have the hardware or are reliant on linear codes – Do not cut customers off of linear codes, they will need some time for them to transition.
- What is preventing transition to 2D barcodes completely?
  - There is a focus on customer needs and what they need to do their work today.
  - Some manufacturers in the group would be able to change all of their lines immediately to 2D if the users were ready to adopt and that the process was ready to go, although this was not universal across all manufacturers.
  - Some integration with EMR/ Practice Management Software (PMS) is needed. Manufacturers need to adopt this at once. It does no good to have a scanner gun if the system has no place to put the values. A majority of packages do not have the ability to support locally and that is going to need some time to come around.
- Note: How many users are scanning/using linear codes on the primary packages?

4. Where would the 2D barcode need to be located to drive maximum benefit?

- Unit of use? Yes.
- Consider placing the barcode so that you do not introduce safety issues relating to how the user/nurse is handling the vial/syringe.
- It will be important to solicit perspectives from all different kinds of users during the pilot. This should be discussed this at the future educational forum to define what the most convenient location to place the bar code would be and to ensure it works for larger packaging etc.
- Provide manufacturers with clear direction from the user community on where the best placement is for the bar codes.
- What works best at the secondary packaging level – in terms of users bringing inventory into the system as well as individual administration?

5. What educational campaigns will increase adoption?

- CDC and the National Vaccine Program Office (NVPO) should champion the significant improvement in safety. Need to be leaders to promote the concept.

- Payers, EMR and PMS Vendors need to be involved and may require setting performance thresholds (Healthcare Effectiveness Data Information Set (HEDIS)) and that credit will not be provided unless you submit a complete record instead of a partial record.
- Greater level of requirements around Stage 2 meaningful use (vaccine safety). Need a little more teeth because that stick will drive the EMR vendor community to incorporate into products if it is a requirement to stay certified under those programs.
- AAP/others can provide continuing education (C&E) opportunities to communicate financial savings to members (webinars etc.). AAP section about improving practice management.
- Timing is important (not too quick and not too late). Don't want to educate now before you are ready to go because people get excited and they cannot do anything with it. Don't want to be too late because you want a chance to build up momentum.

User adoption parking lot:

- Note ICD 10 conversion Oct 2013 will be a major distraction for vendors/providers. Whatever happens needs to precede this because there will be a lot of noise around that and we want to avoid fighting for attention. Don't want to get lost in the noise.
- Packaging form? – is it worth exploring alternate solutions for inventory? Putting barcode on a package slip?
- Considerations around serialization – track and trace.

Group 3 -Time and Cost

The focus of Group 3 was to discuss the time and cost considerations and challenges facing manufacturers when considering adoption of 2D barcoding. The questions asked of the group and the related discussion points are below:

1. **What are the benefits for manufacturers to adopt 2D barcoding? What is preventing the complete transition to 2D barcodes?**
   - Eliminating peel off labels could be a factor, and eliminating linear would simplify labeling.
   - 2D is a heavy foundation for larger implementation of data and followed by serialization. Once implemented at the primary container level then expanding to secondary package or case will be a good transition for manufacturers.
   - Conversion is limited by the slowest adopter – manufacturers have their reasons for not moving this forward, such as unit volume. Packaging lines are busy between May and October because of seasonality, and freeing up lines to validate would be a significant risk.
   - Knowing that you need to plan ahead for other adjustments as part of a larger, strategic plan.
   - Concern about investing in 2D but users lagging in adoption.
   - 2D could be replaced by a new technology – radio frequency identification (RFID) was set aside, but at some point 2D could lead to another answer.

2. **Where would the 2D barcode need to be located (packaging – primary/secondary) to drive maximum use and benefit? To distributors/wholesalers? To providers?**
    - Greater flexibility to change secondary packaging.
    - A federal date would increase action – realm of coverage leaves off with manufacturer because hospitals and users don't fall under FDA realm. Question about the impact that the FDA could have, given that they don't control all the way down to the patient, like other countries do.
    - Allowing a single regulatory submission for multiple products would facilitate transition, but
        - This is likely unrealistic because vaccine products are looked at individually, therefore putting together a group's submission would not necessarily have a positive response. FDA review is not set up that way.
        - Most submissions will be highly similar.
        - An issue with a single part of a multiple submission could delay approval – if submitting 2D barcoding changes with other changes to labeling or package insert.

3. **How are federal regulations or lack thereof, impacting the adoption of 2D barcoding?**
    - All changes in the production process bring a regulatory process—this adds additional time to the impact timeline – not only do you have manufacturing changes, but regulatory submissions after the manufacturing changes. A complete validation package needs to be finished prior to notification of the FDA. If lumped together with other changes, the FDA would not necessarily give approval upon notification.
    - User adoption is necessary to realize benefits. Both sides should work towards goal.
        - Manufacturers often face regulation even when users are not using changes. Manufacturers make submission as a lever to drive the future. Whether or not other users decide to implement is not a regulatory function – this may be done piecemeal – but not something that can be leveraged.
        - Florida is a case study of this – there was a demanding pedigree system and because users were not using the system, this fell apart.
        - Can we create a carrot for users? For EMRs?
    - Regulatory notice facilitates planning.

4. **What cost and time impacts should be considered when transitioning from linear to 2D barcoding?**
    - Planning phase is essential because changes implicate capacity.
        - High opportunity cost of shut downs and seasonal changes (400 vaccines/minute)
        - Planned downtime is often already allocated.
        - Time estimate: 3-4 weeks of downtime for installation and validation of equipment.

- Seasonality of product (May-September is high burn) – has to do with immunization plans for kids.

- Suboptimal options exist (e.g. offline labeling) where labels are applied in high speed and then brought to labeling after the fact.
- Implementing validation online with current capacity and current products is complicated – interweave with upgrading and validation plan.
- Changes are often global moves.

5. **How will software/hardware vendors that are not supporting 2D barcoding factor into your adoption?**
    - Enterprise Resource Planning (ERP) systems are capable of handling 2D barcodes because information is not changing – Universal Product Code (UPC) is transitioning to GTIN with lot and expiration date and these fields exist today in ERP systems.
    - Serialization is driving bigger changes.

The use of contract manufacturing was not openly discussed but this was a consideration.

7.0 Summary & Follow-ups

Summary

There were many key lessons learned from the forum and the Pilot team identified several which will continue to be focal points for the industry. As the discussions continued throughout the day, it was clear that:

- Manufacturers recognize the value of 2D barcoding to the provider community, but struggle with implementing in a cost effective way.
- There is confusion and concern about regulatory requirements slowing rapid adoption. The FDA is willing to address and work with the manufacturers to resolve.
- There will be a period of time where all vaccine products will carry both linear and 2D barcodes, until there is sufficient uptake of 2D symbology by providers and migration away from linear barcodes.
- GS1 is the standard that manufacturers have adopted for use in the supply chain.
- Forum participants welcome the opportunity to work collaboratively with agencies and peers on defining the benefits and seeking ways to solve issues and enhance patient safety. Additional forums are suggested which also include providers and EMR vendors.
- There is a need for alignment between vaccine manufacturers and vaccine end-users, or immunizers. Manufacturers cannot drive the adoption of 2D barcoding alone.

A survey was also distributed to all attendees in order collect feedback on the forum and what could be done to enhance the education and insight gained from the event. Results from the surveys are displayed in Appendix F.

Follow-ups

Several items throughout the forum were noted with a need for follow-up. These items were:

- **Barcodes on VIS:** Determine the optimal training and technical assistance approach for instructing health practitioners when to scan VIS barcodes.
- **2D Barcode Exemptions**: CDC/FDA needs to communicate to manufacturers whether a 2D barcode exemption will be required for each product they offer or if only one exemption required that would apply to all products.
- **Combination Products:** No clear answer emerged during the forum on which of the lot number for a combination vaccine product should be captured. This could be a topic for a future focus group or a future forum.
- **Location for Barcode Placement**: Discuss location at the future education forum to define what the most convenient location to place the bar code would be and to ensure it works for larger packaging etc.

8.0 Appendices

Appendix A – Web Links to Speaker Presentations

Welcome - Dr. Anne Schuchat, MD CDC

Overview of 2D Vaccine Barcoding Pilot - Dr. Erin Kennedy

Overview and Guidance on Vaccine 2D Barcoding - Captain Vada Perkins

Industry Goals and Progress for Vaccine Barcoding - Perspective from AAP - Dr. Edward Zissman

Overview of Vaccine Bar Coding Report - Alan O'Connor

Emerging Standards for Vaccine Barcoding - GS1 Overview - John Roberts

Appendix B – Forum Sponsors

For the Manufacturers Forum, sponsorship was defined as providing support and endorsement of the overall objectives of the Manufacturers Forum as well as the 2D Vaccine Barcoding Pilot. Each of the sponsoring organizations provides a critical link in the vaccine supply chain and is dedicated to the health and safety of patients. The organizations below were not compensated for the use of their logo or for participation. A summary about each of the participating organizations is provided below.

- American Academy of Pediatrics (AAP)
- Association of Immunization Managers (AIM)
- American Immunization Registry Association (AIRA)
- GS1

Appendix C –Attendees

In Person Attendees

Attendee	Organization	Role
Adamusik, John Thomas	Celgene Corporation	Director, Package Development
Anderson, Gregory H.	Connexin Software Inc.	CIO
Bennett, Laurie B.	McKing Consulting Corp	Consultant
Bridges, Carolyn B	CDC	Assoc Dir Adult Immunizations
Charles-Rennie, Trisha	McKing Consulting Corp	Mtg. Planner
Chen, Robert	CDC	HIV Vaccine & Special Studies Team Leader
Crowley, John Jay	FDA	Senior Advisor for Patient Safety
Durbin, Joseph F	McKing Consulting Corp	Project Manager
Esbitt, Deborah	CDC	Health Scientist
Fish, Rebecca J.	GlaxoSmithKline	Senior Director, US Vaccines
Flynn, Raymond	Novartis Vaccines & Diagnostics	Head of Distribution and Customer Service
Friedman, David	Deloitte Consulting LLP	Principal
Gerlach, Kenneth Allen	CDC - NCIRD	Health Scientist
Glauser, Geoffrey	HHS/ASPR/BARDA	Program Manager
Hill, J. Howard	CDC-MCKING	Sr. Management Consultant
Hosbach, Phil	Sanofi Pasteur	Vice President, Immunization Policy
Jurrens, Erika Leigh	GlaxoSmithKline	Vaccine Futures Manager
Kemp, Craig Charles	Merck Vaccines	Leader, Customer Solutions
Kennedy, Erin D	CDC	Medical epidemiologist
Kewson, Karl Andrew	Novartis Vaccine & Diagnostics	Sr. Packaging Engineer
Kiefer, Brian	Deloitte Consulting LLP	Senior Consultant
Kirkwood, Bonni	Deloitte Consulting LLP	2D Barcoding Vaccine Pilot PM/ SCI Lead
Lease, Christian	Novartis Vaccines	Director, Immunization Policy
Lee, Brian E.	Merck	Technical Service manager
Malhame, Melissa	Dynavax Technologies	Sr. Director
Maloney, Diane Marilyn	FDA/CBER	Associate Director for Policy
Masland, Duncan	Deloitte Consulting LLP	Business Analyst
McDaid, Kenneth B.	Merck	Customer Manager
O'Connor, Alan C.	RTI	Senior Economist
Papageorgiou, Nikos	Deloitte Consulting LLP	Sr. Consultant
Patel, Anita	CDC	Health Scientist
Paster, Jennifer L.	Sanofi Pasteur	Deputy Dir., New Products, U.S.
Perkins, Vada A.	FDA/CBER	Staff Chief, Business Operations, CBER/ADRM
Rieker, Denise	Sanofi Pasteur	Director, Regulatory Affairs
Roberts, John Joseph	GS1 US	Director-Healthcare

Attendee	Organization	Role
Robinson, Paul	Deloitte Consulting LLP	Manager
Scally, Mark Joseph	McKing Consulting Corp	Project Manager
Schuchat, Anne	CDC	Dir. NCIRD, RADM/USPHS, Ast. Surg. Gen.
Shimabukuro ,Tom T	CDC	Senior Medical Officer
Simmons, Anne Louise	GlaxoSmithKline	Manager
Singh, Rajesh	Deloitte Consulting LLP	Manager
Snyder, Michael	Sanofi Pasteur	Equipment Engineer
Squires, Robert Elliott	MedImmune	Director Supply Chain Logistics
Tusavitz, Elysia L.	GlaxoSmithKline	Assoc Director, Reg Affairs, Vaccines
Williams, Warren G.	CDC	Health Analyst
Zissman, Edward Neal	Altamonte Ped. Assoc.	Pediatrician CEO

Webcast Attendees

Attendee	Organization	Role
Ast, Robert	Deloitte Consulting LLP	Senior Manager
Clark-Gagne, Julie L.	Deloitte Consulting LLP	Public Health Analyst
Das, Sharnali	Deloitte Consulting LLP	Consultant
DeLuca, Ruth A.	BIO	Mgr, Science and Regulatory Affairs
Garman, Patrick M.	Military Vaccine Agency	Deputy Director, MILVAX
Gellin, Bruce	Dept of Health & Human Serv.	Deputy Assistant Sec for Health and Director
Granados, Gil C.	Sanofi Pasteur	Director Regulatory Labeling
Hay, Catherine Ann	MassBiologics	Assoc. Deputy Director, Reg. Affairs
Hoover, Bethany Dalton	BioMarin Pharmaceutical	Sr. Manager Supply Chain Integrity
Kerls, Daniel	CVS Caremark	Director of Ambulatory Operations
Laymon, Barbara	Deloitte Consulting	Public Health Analyst
Lundrigan, Karen Ann	Alberta Health and Wellness	Provincial Coordinator, Biologics
Lynch, Michael John	Pfizer Vaccines	Product Director
Marsh, Timothy Robert	Pfizer	Senior Manager
Meek, Drew	WHO	Doctor
O'Leary, Melinda Lu	GlaxoSmithKline	Packaging Manager
Rivera, Wilfredo	MedImmune	Secondary Process Industrial Engineer
Svaby, SueAnn	NextGen	Design Analyst
Sumner, Chris	Pfizer Vaccines	Product Director
Weiss, Holly M.	GlaxoSmithKline	Dir. Service/Solutions/Cust. Experience

Appendix D – Forum Working Session Groups

Standards Group 1	User Adoption Group 2	Cost and Time Group 3
John Roberts, GS1	Edward Zissman, MD – AAP	Rebecca Fish, GSK
Raymond Flynn, NVD	Greg Anderson, Connexin	Andrew Kewson, NVD
John Adamusik, Celgene	Mike Chaney, AAP	Kenneth McDade, Merck
ElysiaTusavitz, GSK	Erika Jurrens, GSK	Anne Simmons, GSK
Brian Lee, Merck	Craig Kemp, Merck	Phil Hosbach, Sanofi
Jennifer Paster, Sanofi	Christian Lease, NVD	Alan O'Connor, RTI
Melissa Malhame, Dynavax	Denise Rieker, Sanofi	Ken Gerlach, CDC
Warren Williams, CDC	Erin Kennedy, CDC	Deborah Esbitt, CDC
Anita Patel , CDC	Robert Squires, Medimmune	Michael Snyder, Sanofi
Facilitators and Scribes		
Rajesh Singh	Joe Durbin	Paul Robinson
Brian Kiefer	Nikos Papageorgiou	Duncan Masland

Appendix E – Challenges Suggested by Forum Registrants

Standardization	User Adoption	Cost and Time Commitment
<u>Opportunities</u> • Standardization of barcode information content • Extending standards from US to worldwide given global use of vaccines <u>Challenges</u> ▪ Consistency of provider data capturing and sharing ▪ Consistency of implementation across manufacturers ▪ Alignment with US and global serialization (i.e. GTIN) and technology standards ▪ Master data management, structure and ownership ▪ Understanding a timeline and expected rollout for universal adherence ▪ Will there be a standardized information requirement that all companies need to adhere to? ▪ Prepping the market for successful implementation in the face of many different platforms, including multiple EMR systems and multiple state registries with various data	▪ Coordinated education campaign to increase HCPs adoption ▪ Communication of the benefits realized ▪ Enabling 2D scanning at HCP sites ▪ Consistency of data capturing and sharing across providers ▪ Existing stockpiles delay the adoption of the new technology ▪ Defining success with the customer: managing customer expectations with a phased launch approach while still encouraging adoption	▪ Production capacity loss due to speed reduction ▪ Manufacturers' investment in 2D enabling equipment ▪ Low utilization of newly purchased (non-2D enabled) equipment ▪ Cost of provider technology adoption ▪ Online grading and line speed equipment manufacturers are still not supporting 2D barcoding ▪ Label real estate

Figure 1 – Most often identified challenges and opportunities identified by forum registrants

Supply Chain Improvements – Supply chain improvements include gaining efficiencies, reducing errors, and increasing visibility to product and inventory across and between all supply chain partners.

- Information Exchange – Described as increased data and information sharing and integration which enable more efficient and accurate transactions and patient safety information.
- Internal Consensus – Often mentioned by manufacturers when developing strategy and implementation plans to incorporate 2D barcoding on vaccine products. This involves communicating to internal stakeholders, identifying the associated costs and benefits and prioritizing the capital expenditures towards supporting needs.
- Regulatory Requirements –Regulatory requirement challenges are often mentioned in the context of changes and complexity. Regulations may be open to interpretation and costly/difficult to implement when misaligned with current technology capabilities and standards. The extended approval timeframes of labeling also creates challenges for quick turnaround and implementation. In general, vaccine providers are not familiar with regulatory requirements and their impact on processes and patients.
- Miscellaneous – Marketing and the enhanced use of barcoding beyond administration and inventory were mentioned as opportunities.

Figure 2 depicts the balance of the opportunities and challenges submitted by Forum participants as described above.

Opportunities	
Supply Chain Improvements	▪ Increased immunization coverage and public health levels ▪ Reduced provider vaccination errors ▪ Increased traceability of batches ▪ Improved AEFI reporting (adverse event reporting) ▪ Enhanced inventory control
Information Exchange	▪ Integration of vaccination records into clinical information systems (EMRs/EHRs) ▪ Quick, paperless data sharing ▪ More efficient tracking of immunizations that can be downloaded into registries ▪ Elimination of human error such as transposing digits ▪ Improve tracking of vaccine exposure information for epidemiologic studies of vaccine safety and efficacy
Miscellaneous	▪ Marketing to pediatricians and other immunizers ▪ Enabling use of cell phones for scanning barcodes ▪ Enhanced customer service
Challenges	
Internal Consensus (Manufacturers)	▪ Communicate to corporate partners the need to ramp up quickly ▪ Business value for manufacturers to adopt 2D codes is still unclear ▪ What are the additional benefits beyond patient administration ▪ Costs in terms of time and resources can be prohibitive ▪ Implementing online printing equipment at all contract packagers used
Regulatory Requirements	▪ Technical alignment with FDA requirements is lagging ▪ FDA regulations on barcoding are not enforceable at the hospital, pharmacy or clinician office ▪ Ability of providers to abide with evolving requirements

	▪ Labeling approval ▪ Developing clear steps for filing a waiver with the FDA and creating a clear definition of the change category

Figure 2 – Additional challenges and opportunities identified by forum registrants

Appendix F – Forum Evaluation Feedback Results

A survey was distributed to all attendees of the forum in order collect feedback on the forum and what could be done to enhance the education and insight gained from the event. The survey document is included below:

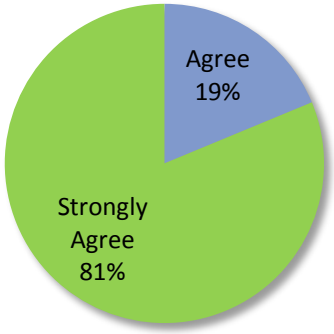
Manufacturers Forum Survey

A total of 16 surveys were completed and collected. While many of the attendees left before the forum ended, the feedback from the surveys received has been aggregated.

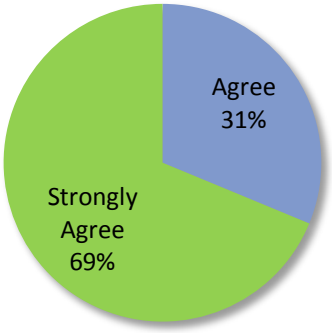
Results Summary: Forum Content and Materials

Survey results showed that overwhelmingly, the attendees were satisfied with the content and structure of the Forum with the breakout sessions universally acknowledged as one of the most useful portions of the event. In terms of attendees' understanding of key concepts presented at the Forum, there is a fair amount of work to be done in the standards area, especially around combination vaccine packaging and placement of barcodes. While there is significant expectation on clear FDA guidance on packaging standards, overall the attendees felt that they gained a better understanding of opportunities and challenges around 2D Vaccine Barcoding from the Forum.

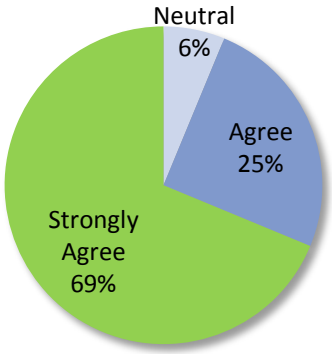
Question1: This forum provided an effective opportunity to discuss the implications, opportunities, and challenges of implementing 2D barcoding technology on vaccine products.



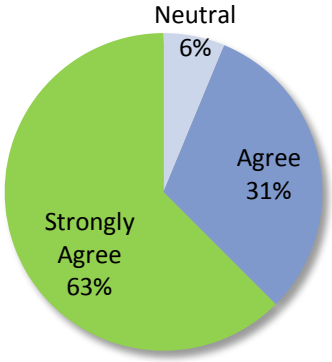
Question 2: The forum materials were clear, helpful and easy to follow.



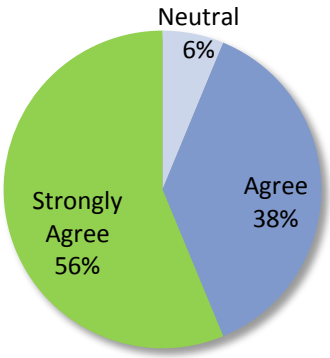
Question 3: The breakout sessions allowed for productive discussion and provided appropriate interaction.



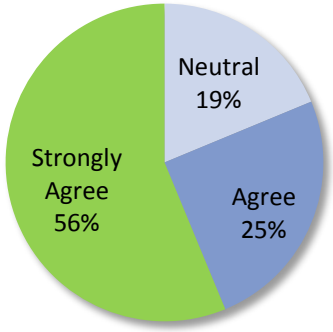
Question 4: The facilitators effectively presented workshop materials and led group discussions.



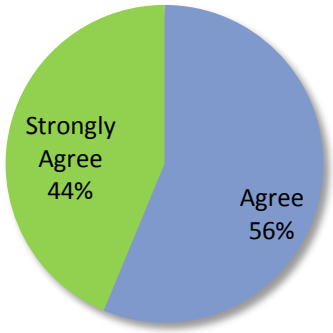
Question 5: I have a better understanding of industry standards relevant to 2D barcoding technology on vaccine products.



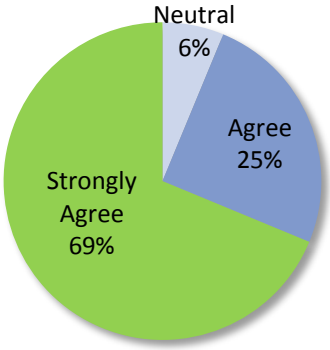
Question 6: The forum clarified the FDA expectations for linear barcode review and acceptance process.



Question 7: I have a better understanding of the standards available related to 2D barcoding technology on vaccine products.



Question 8: I have gained a greater understanding of the opportunities and challenges of implementing 2D barcode technology on vaccine products.



Eleven of the 16 surveys included additional free form responses capturing the benefits attendees saw from the forum as well as opportunities for improvement.

What are the greatest benefits?	▪ Patient Safety: 2 ▪ Supply Chain Integrity: 1 ▪ Competitive Advantage: 2 ▪ Agency Alignment: 1 ▪ Foundation for Serialization: 1
What are the greatest challenges?	▪ User Adoption: 4 ▪ Contract Manufacturer: 2 ▪ Regulatory & Guidance: 4 ▪ Line Impact: 3 ▪ Serialization Conflict: 3
What aspects need further investigation?	▪ Co-packaging/placement: 6 ▪ Drivers for user adoption: 2
What was the most valuable part of the forum?	▪ Breakouts: 11
What could have been better?	▪ Nothing: 7 ▪ Should have been longer: 3 ▪ Bring in other stakeholders (Immunizers, EMR Vendors): 2