

The project team thanks the reviewers for their public comments on “Achieving Unique Device Identifiers in Real World Data Sources: A Playbook for Health System Unique Device Identifier Implementation at the Point of Care” We appreciated the thoughtful comments.

We have incorporated some of the suggestions and feedback to strengthen our work. Others were beyond the scope of the Playbook. In summary, the comments were very helpful in considering next steps for enabling an RWE generation system for medical devices that is supported by the UDI.

Overarching comments:

- We appreciate the commenters’ support of advancing UDIs.
- We recognize that more work for UDI implementation at the POC and UDI use needs to be done and that unresolved barriers and issues remain. However, the goal of our work was review and aggregation of information from published research, reports, and case studies on health system UDI adoption, in order to create a guidance document for health systems to implement UDI at the POC.
- We also recognize that the policy landscape is dynamic. The Playbook was not intended to debate various policies or policy efforts, rather to acknowledge their presence and share relevant published findings.
- We have specifically added how UDI can help support reduction of missing revenue.
- We have specifically added the importance of interoperability between IT systems, as well as the need for collaborative efforts to facilitate transparency of available IT systems that best support UDI implementation in health systems, interoperability between IT systems from different vendors, and movement towards an “out of the box” interoperable IT solution.
- We agree that there are opportunities for innovation to optimize the necessary IT infrastructure as well as needed next steps to address gaps and barriers. We have added a high-level comment in this regard. As IT systems evolve, strategies for implementing UDI will also likewise evolve.

Thank you again for your public comments.