

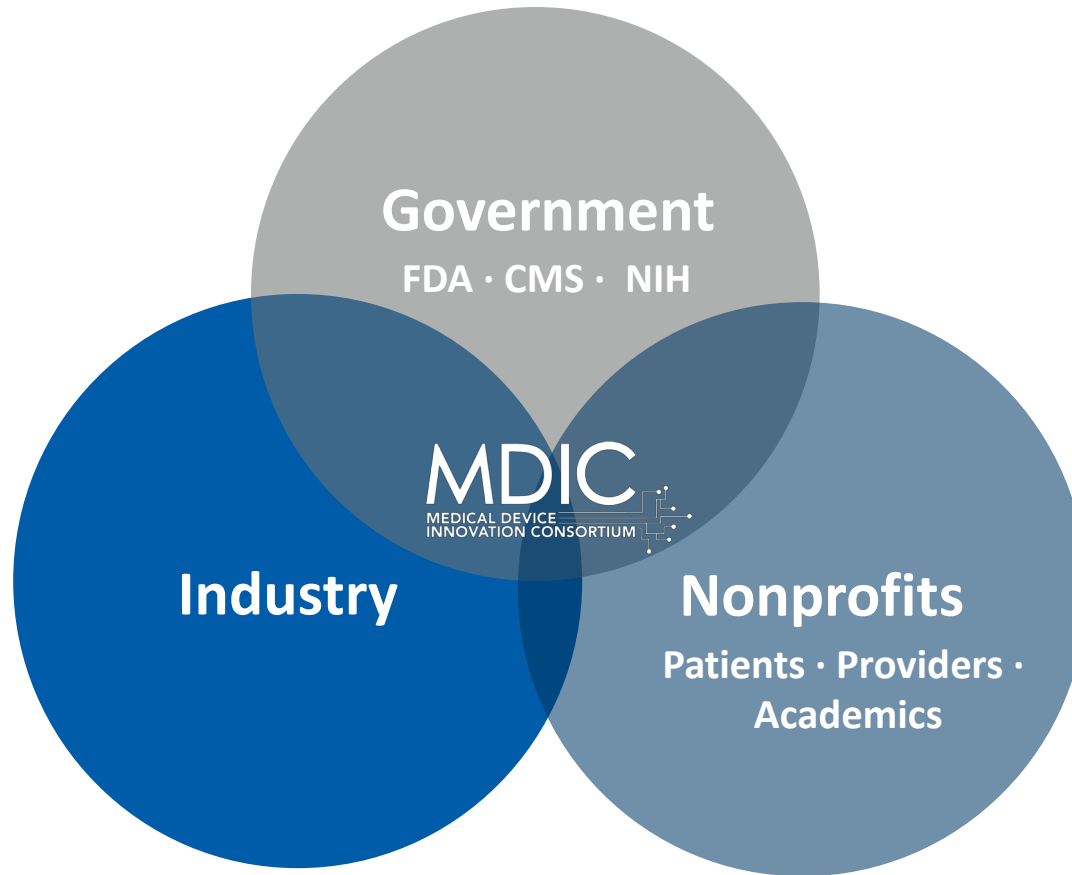
MDIC AND FDA: PARTNERING TO INCREASE PATIENT ACCESS

Pamela Goldberg, President and CEO

November 16, 2018

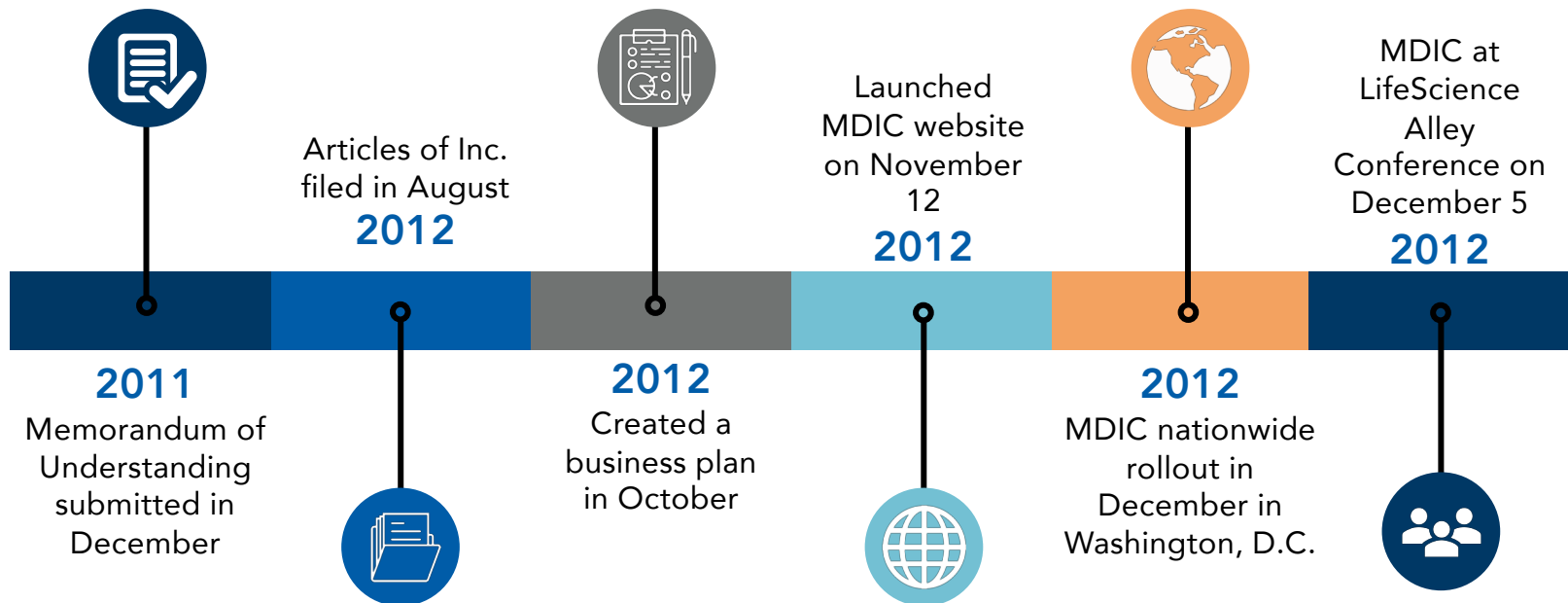


A PARTNERSHIP TO IMPROVE THE FUTURE OF PUBLIC HEALTH

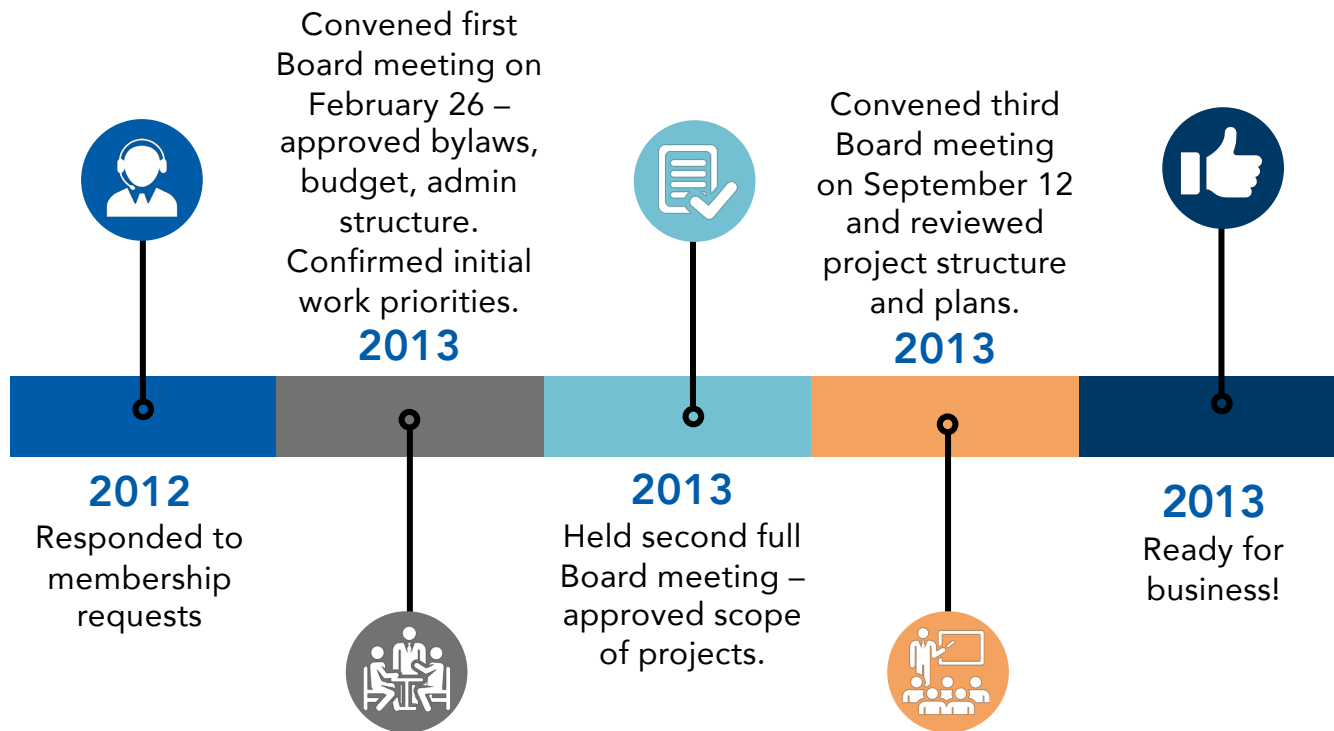


Resources • People • Intellectual Capital

THE DEVELOPMENT OF MDIC



THE DEVELOPMENT OF MDIC





"What we've lacked is a structure like the Medical Device Innovation Consortium that allows for a larger number of parties to come together to develop these projects on an ongoing basis - a significantly more effective way to do research."

***- Jeffrey Shuren, MD, JD
Director of CDRH***

MedPage Today, December 4, 2012

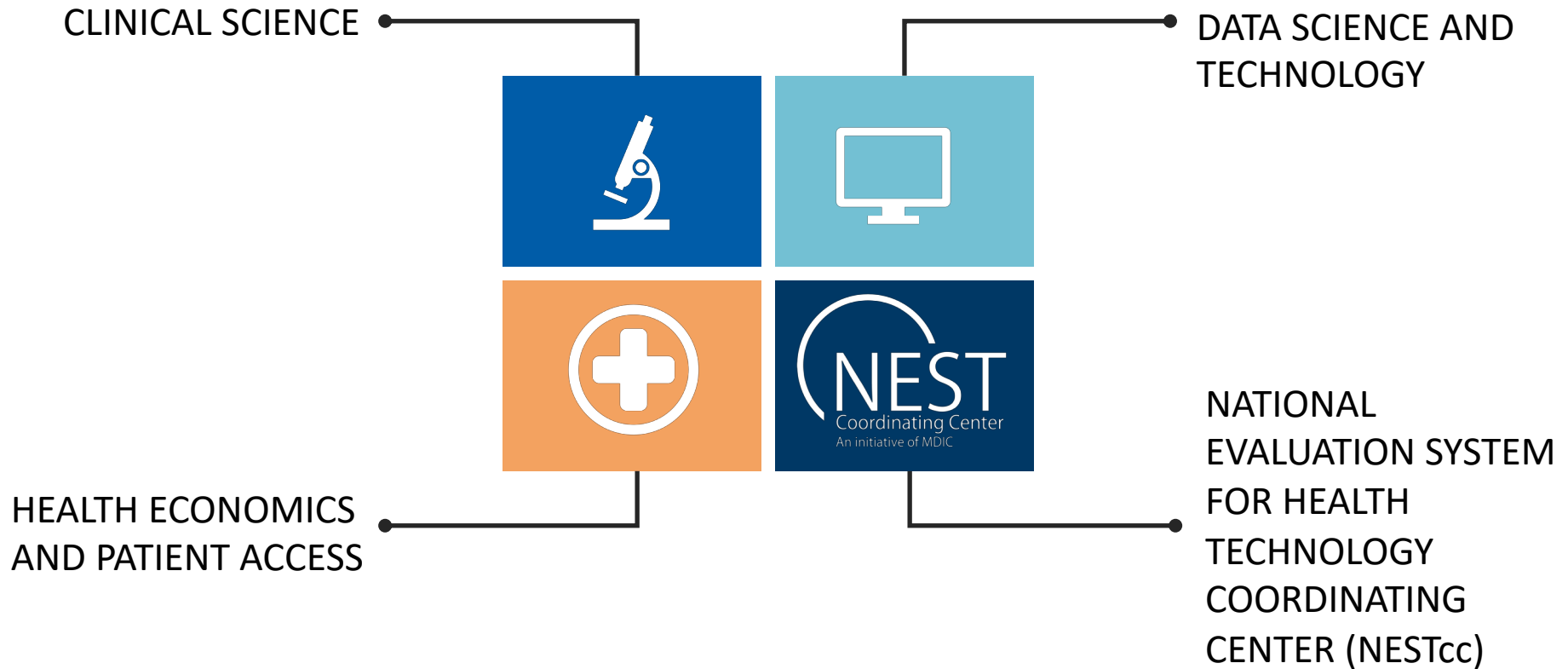


MDIC IS ALIGNED WITH CDRH PRIORITIES



MDIC collaborates with CDRH by developing resources to help assess the safety, efficacy, quality, and performance of FDA-regulated products.

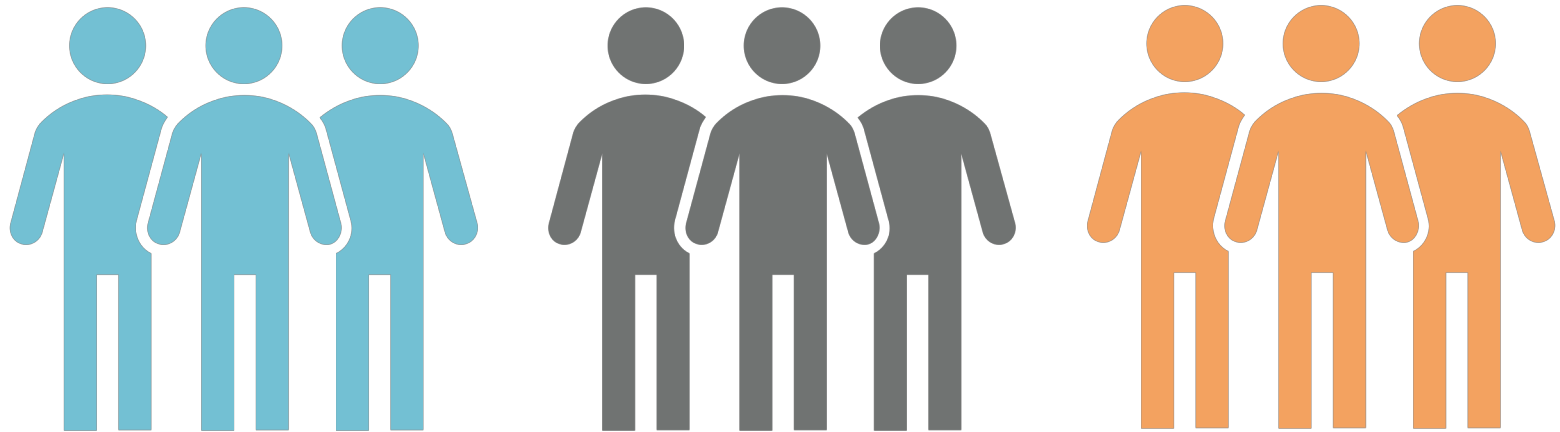
MDIC CORE INITIATIVES AIM TO INCREASE PATIENT ACCESS TO MEDICAL TECHNOLOGIES



MDIC SUPPORTS PROGRAMS TO ADVANCE THE MEDICAL DEVICE INDUSTRY

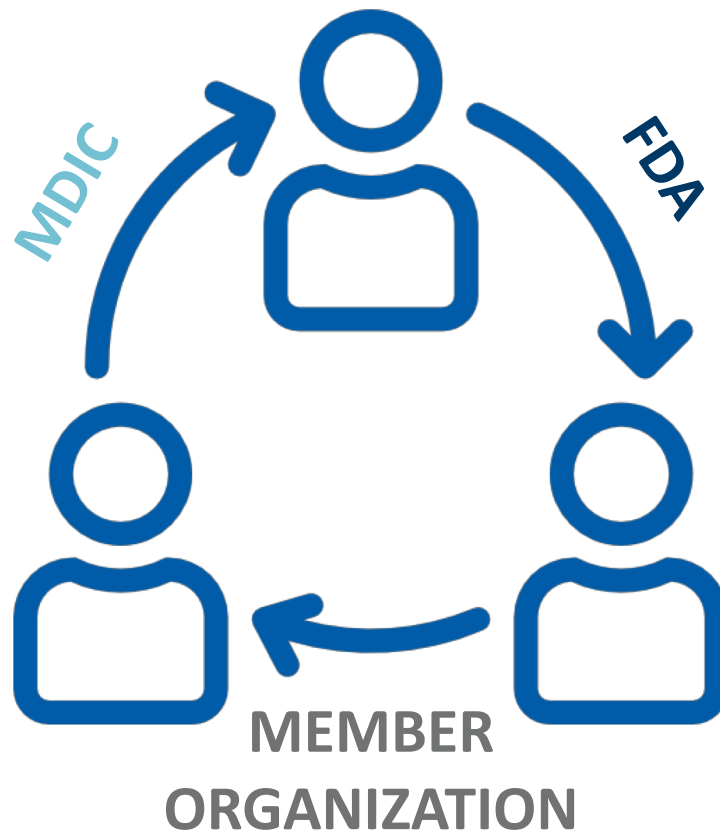
DATA SCIENCE & TECHNOLOGY	CLINICAL SCIENCE	HEALTH ECONOMICS & PATIENT ACCESS	NESTcc
Computational Modeling & Simulation (CM&S) <ul style="list-style-type: none"> Blood Damage Modeling 	Early Feasibility Studies (EFS) <ul style="list-style-type: none"> EFS Metrics & Tools EFS Demonstration Program 	CMS: coverage, coding, and payment methodologies	Governance
External Evidence Methods (EEM) <ul style="list-style-type: none"> Virtual Patient Framework 	Clinical Diagnostics <ul style="list-style-type: none"> <i>In vitro</i> Diagnostics (IVD) Clinical Evidence IVD Real-world Evidence (RWE) Point-of-care Device Study Designs (Fingerstick) Surrogate Samples Somatic Reference Samples (SRS) 	Private payer coverage processes	Data Network
Case for Quality (CfQ)			Test-Cases
Cybersecurity			Data quality and methods
Signal Detection	Coordinated Registries Network (CRN) Development <ul style="list-style-type: none"> Cardiac Devices Pilot (CDCRN) 		

MEMBERSHIP WITH MDIC



MDIC is open to organizations that are substantially involved in medical and/or medical device research, development, treatment, or education; the promotion of public health; or who have expertise in regulatory science.

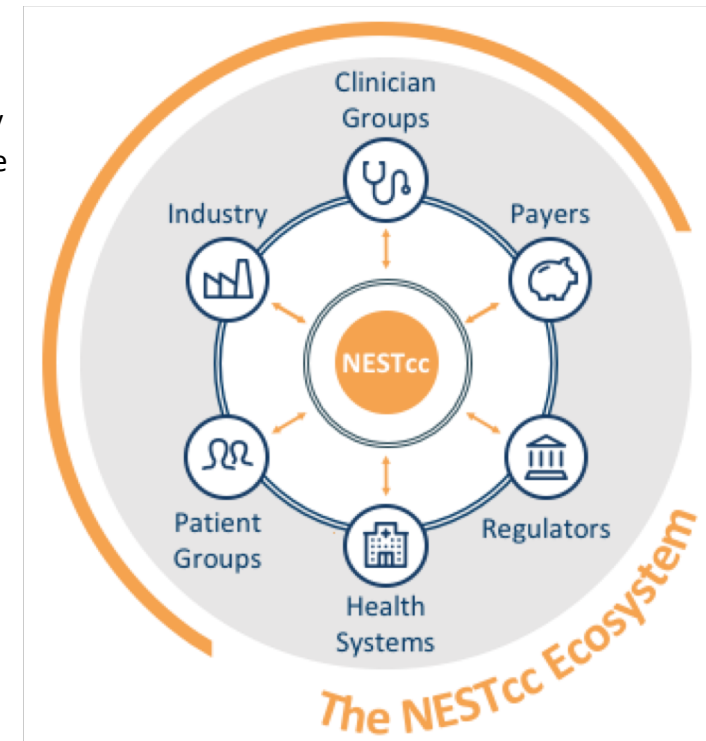
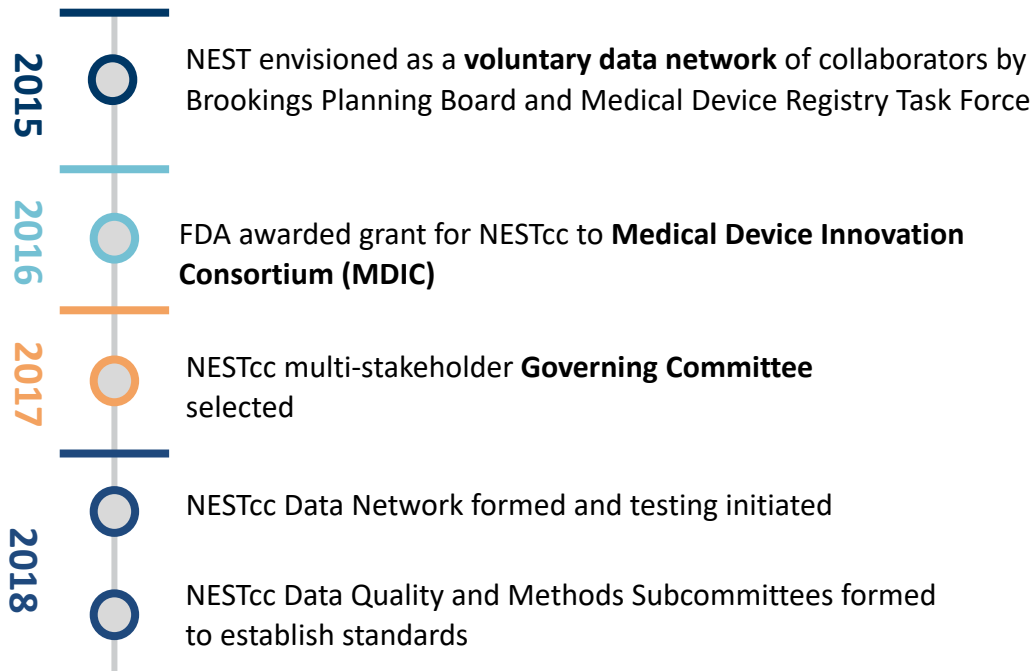
WORKING GROUPS COLLABORATE TO CREATE SHARED SOLUTIONS



LEVERAGING REAL-WORLD EVIDENCE THROUGH NESTcc

MDIC's National Evaluation System for health Technology Coordinating Center (NESTcc) accelerates the development and translation of new and safe health technologies, leveraging Real-World Evidence (RWE), and innovative research.

History of NESTcc





QUESTIONS?



MDIC

**MEDICAL DEVICE
INNOVATION CONSORTIUM**



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Thank You

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