

FDA CDRH's Partner with Patients Strategic Priority

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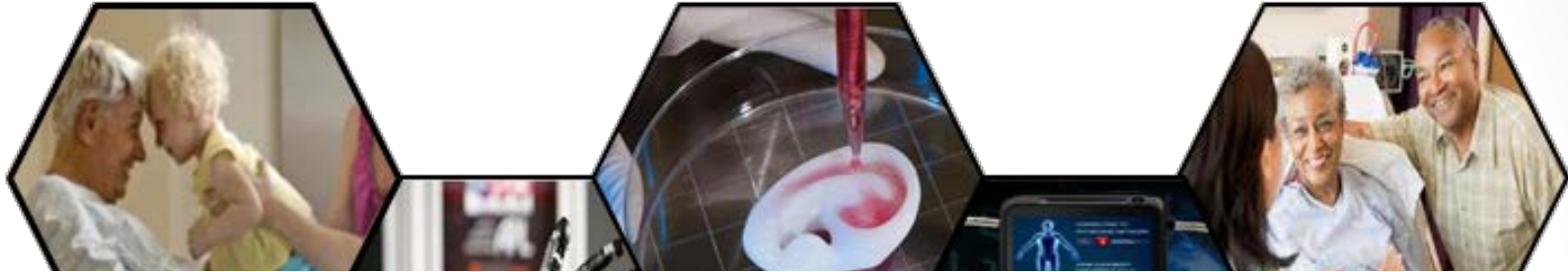
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Patients at the heart of what we do



CDRH Vision: Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world.



2016-2017 CDRH Strategic Priority: Partner with Patients

We must interact with patients as partners and work together to advance the development and evaluation of innovative devices, and monitor the performance of marketed devices.



GOALS

- Promote a culture of **meaningful patient engagement** by facilitating CDRH interaction with patients.
- **Increase use and transparency** of patient input as evidence in our decision making.



Patient Engagement Activities

- CDRH town hall
- Regulatory review division meetings with patient groups
- Site visits
- Research workshop

Science of Patient Input

Patient Preference Information (PPI)

- Inform endpoints or effect size for Regulatory studies
- Inform subgroup considerations
- Labeling changes / expanded indications

Patient Reported Outcomes (PRO)

- Endpoints in Regulatory studies
- Outcomes to monitor postmarket
- Interest to payers, providers, patients

Engagement-Science Synergy



Patients can provide the missing piece to complete the picture of clinical evidence.

Thank You.