The Patient Voice in Generic Drug Development

Integrating the patient perspective in generics

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Disclaimer

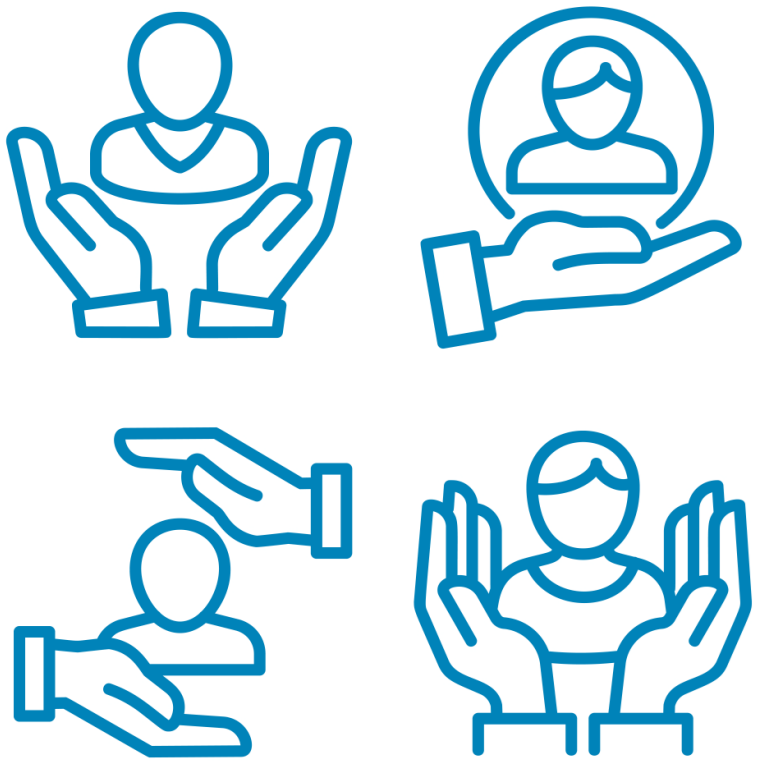
The presentation reflects the views of the presenter and should not be construed to represent the agency's views or policies. The findings and conclusions in these presentations are those of the author

Session objectives

- Show how the generic drug program incorporates patient perspectives
- Translate OGD listening sessions into practical best practices for industry and advocates
- Explain how therapeutic equivalence supports sameness
- Outline measurable outcomes

THE IMPORTANCE OF THE PATIENT VOICE

Patients are at the heart of FDA's work!



- Insights on issues, needs and priorities that are important to patients and caregivers
- Diverse opinions and experiences
- Insights on risk tolerance and potential benefit
- Real world experience

FDA PATIENT LISTENING SESSIONS — AT-A-GLANCE

Engagement Programs

CDER
CDER
Patient-Focused Drug Development

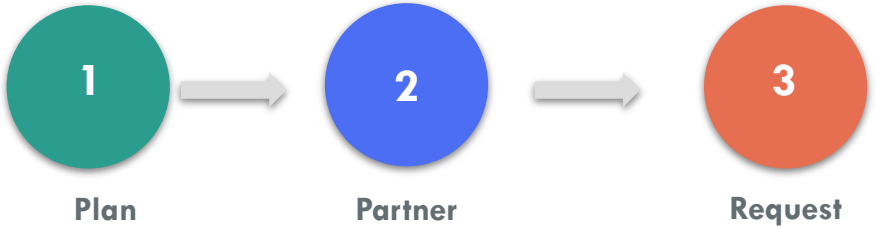
OCE
OCE
Oncology Center of Excellence

CBER
CBER
Patient Engagement

CDRH
CDRH
Patient Engagement & Preference

RARE
Rare Disease Innovation Hub

Plan a Listening Session



- Staff Manual Guide (PLS Policy)
- PLS Overview
- Case Example
- NORD
- Reagan-Udall Foundation
- PLS Home & How-to

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OGD Patient Engagement Opportunities

- There are opportunities to participate in the public meetings held by OGD and other conferences
- Public solicitations for input on the user fee program negotiations

- To request a meeting

FDA Patient Listening Sessions | FDA

Why the patient perspective matters

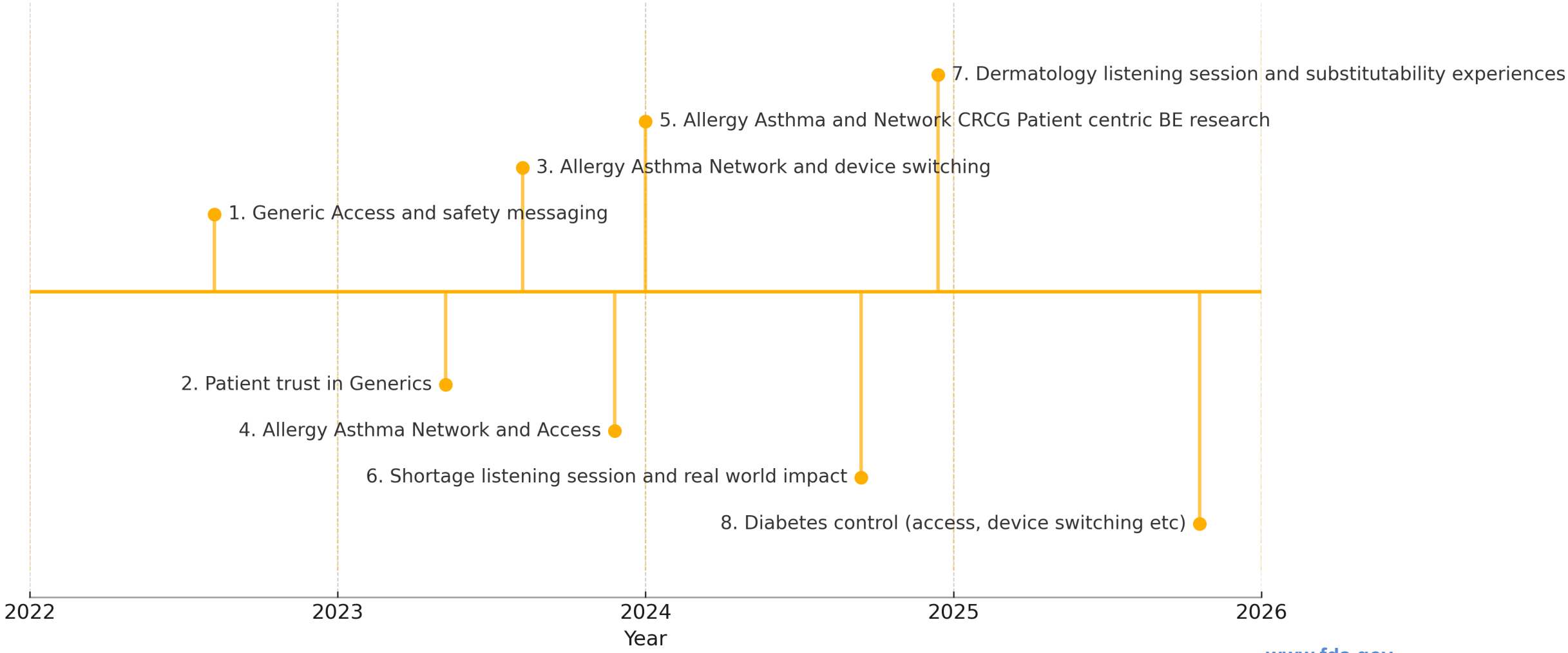
Patients are the end users of products

Usability and real-world behavior drive adherence and outcomes

Trust is earned by clear communication

Generic drug development is stronger **when informed by lived experience**

OGD Patient Listening Sessions Timeline (includes CSD) — Updated



WHAT PATIENTS TOLD US

- Trust in generics exists, confusion about switching persists
- Some device differences can cause initial anxiety and potential confusion
- Cost does not equal access, formulary and supply determine reality
- Patients want timely and clear communication from FDA and sponsors

INTEGRATING PATIENT INPUT INTO GENERIC DRUG DEVELOPMENT

- Patient experiences with brand drug
- Identifying allowable differences and patient preferences
- Research priority-setting

- Unexpected safety considerations and concerns

- Safety reporting
- Drug shortages reporting

OGD PATIENT FOCUSED INITIATIVES

Research grants researching patient and disease-specific views and concerns.

OGD welcomes patient input and held our first patient listening session in 2022.

PATIENT ADVOCACY

- Identify informational gaps and patient needs
- Informational relevance and exclusions
- Align patient needs and preferences
- Avoid costly development errors

- Provide appropriate methods to support patients
- Dedication to help patients make informed decisions
- Promote positive patient behavior and trust
- Higher patient compliance and disease control

U.S. FOOD & DRUG ADMINISTRATION

LIMITATIONS AND HOW WE HANDLE THEM

- Controlled Clinical trials are not admissible in generics
- Generic labeling is generally the same as the reference and must be consistent with law
- FDA does not set coverage, cost sharing, or state substitution rules
- Patient input must be collected with clear methods and privacy safeguards

CENTER FOR RESEARCH ON COMPLEX GENERICS (CRCG) AS A BRIDGE FOR PATIENT VOICE

- Connects advocacy groups such as allergy asthma network (AAN) with industry and academic researchers
- Supports research tracks on patient centered bioequivalence and device usability
- Creates a forum to translate patient feedback into study design and training materials

RECOMMENDATIONS

Developers: involve patient insights in design, support sameness with usability evidence, communicate differences clearly

Advocacy groups: co develop plain language explainers and feedback channels

Academia: study real world use and training burden and share findings in accessible formats

We Are OGD

Ask me why...

"We collaborate beyond our borders to **safeguard our patients."**

"As a single mom in school, I had to find the means to afford my son's pneumonia medication and compromising my son's wellbeing is never an option."

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