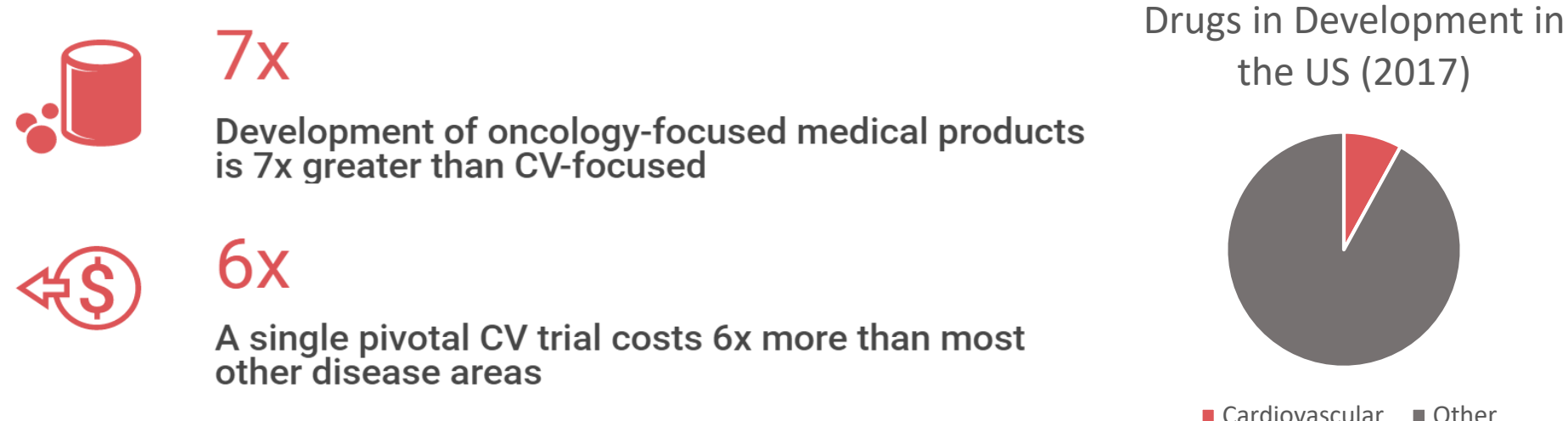


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The Drug and Device Innovation Gap

The medical product pipeline for cardiovascular disease (CVD) is limited compared with many other leading causes of death. Cardiovascular trials are costly and time-intensive.



Short-Term Recommendations

- Ensure outcomes used in end points are meaningful to patients
- Streamline diverse participant recruitment and accessible “site-less” trials
- Patients own, use, and share trial data
- Develop a core CV outcome set

Long-Term Recommendations

- Establish a forum for patient input in research process
- Create a patient advisory group for NHLBI grant offerings

Qualitative Methods

Reviewed public data and literature (including gray/white)

Convened the Partnering with Regulators Learning Collaborative of approximately 30 experts representing diverse stakeholder perspectives to inform key research questions

Analyzed expert Collaborators’ discussion to identify key themes and recommendations

Short-Term Recommendations

- Focus trial innovation efforts toward streamlining phase IV studies with patient-centricity
- NHLBI-funded implementation studies on adherence, uptake, decision aids, and risk/benefit communication
- Standardize data collection and analysis

Long-Term Recommendations

- Research how smartphones, wearables, AI, etc. can improve uptake and adherence in diverse populations
- Fund research for integrating various data sources for trial evidence

Short-Term Recommendations

- FDA/CDER forum similar to FDA/CDRH’s Payor Communication Task Force for feedback on new submissions
- Regular AHA convening on innovation in trial design for industry stakeholders, researchers, regulators, and others

Long-Term Recommendations

- NIH-funded research on patient-centered outcomes for trial use
- Capture patient-centered and –generated data in existing CV registries

Real-World Evidence and Data for Innovation
Improve currently licensed products

Improve the Cardiovascular Research and Trial Process

Meaningful Evidence Generation
For patients, payers, and regulators

Expanded Research Community

Short-Term Recommendations

- Create research collaboratives of excellence to recognize quality research
- NHLBI recognition of regional research collaboratives
- Establish community research network to boost engagement, focusing on community-based providers and underserved populations

Long-Term Recommendations

- FDA guidance for stronger and broader equitable inclusion of women and racial and ethnic minorities in clinical trials
- Research building trust in the medical and research establishment to better include underserved community settings

Research Objectives

- Describe the landscape** of CVD research and development
- Identify opportunities** to...
 - Improve equity in and
 - Reduce the cost and complexity of
 ...CVD drug and device research, development, and trials
- Make short- and long-term recommendations** to improve CVD research, development, and trials, thereby expanding CVD drug and device innovation

Patient-Centered Research

Opportunities for patient involvement in early stage research of medical products

Patient-Centered Research and Development

Research Priorities

- Gap analysis
- Identifying unmet needs
- Defining patient priorities and preferences
- Defining target population

Research Design

- Relevant endpoints
- Balancing risks and benefits
- Patient-reported outcomes
- Practical considerations and logistics planning
- Adherence measures
- Readability of informed consent
- Ethical review

Sources of Funding

The American Heart Association Partnering with Regulators Learning Collaborative is part of the broader Value in Healthcare Initiative, a collaboration of the American Heart Association and the Robert J. Margolis, MD, Center for Health Policy at Duke University. The broader Value in Healthcare Initiative is supported in part by the American Heart Association and industry partners (Amgen, Bristol-Myers Squibb, the Bristol-Myers Squibb-Pfizer Alliance, and the Sanofi-Regeneron Alliance). American Heart Association volunteers (clinicians, patient representatives, and other experts) received reimbursement for travel to project meetings, but no other compensation was provided to Learning Collaborative members. The views of this article do not necessarily represent the views of the Learning Collaborative members or the organizations that they represent. Learning Collaborative members provided feedback on the content of this article, but the content of the article was independently determined by the Duke-Margolis Center, which is part of Duke University, and as such honors the tradition of academic independence on the part of its faculty and scholars. Neither Duke nor the Margolis Center takes partisan positions, but the individual members are free to speak their minds and express their opinions regarding important issues. The Duke-Margolis Center received funding from the American Heart Association for this work.

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