Vital Signs

The Crisis in Investment in U.S. Medical Innovation and the Imperative of FDA Reform

Confidential: Do Not Distribute Prior to October 6, 2011

Survey Findings

October 2011

Table of Contents

- **Summary and Methodology**
- **Survey Results**
- **Demographics of Survey Respondents**

Summary

A 2011 study found that U.S. venture capitalists have been and will continue to:

- **Decrease their investment in biotechnology and medical device start-ups**
- **Reduce their concentration in critical therapeutic areas, and**
- **Shift focus away from the United States towards Europe and Asia**

FDA regulatory challenges were identified as having the highest impact on these investment decisions.

We must act now or lose our leadership position in medical innovation, job creation and access to life-saving treatments in the United States.

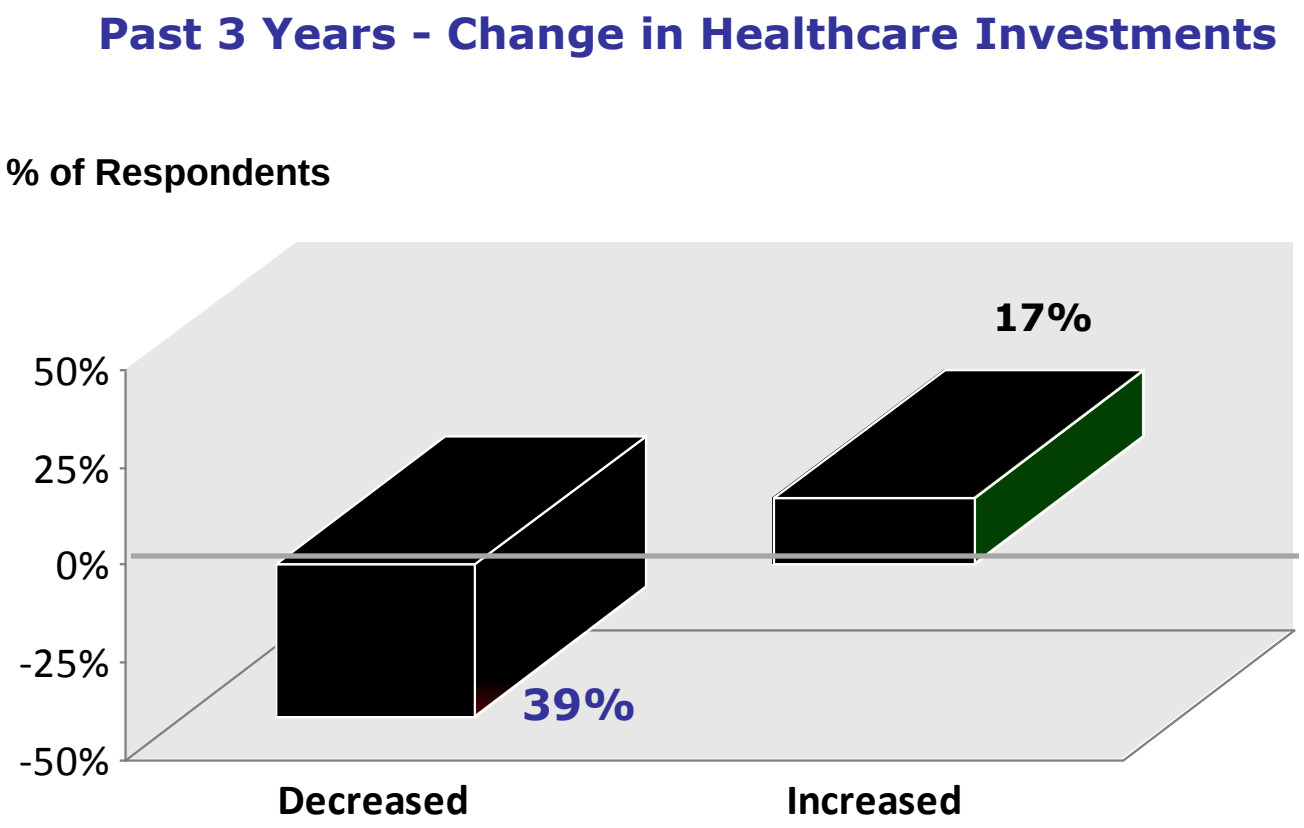
Study Methodology

- **Online survey conducted July–September 2011**
- **Sent to 259 NVCA member firms investing in the healthcare sectors**
- **156 firm responses = 60% response rate = 92% of NVCA invested capital (2008-2010)**
- **Survey respondents accounted for $10 billion of VC investment in healthcare companies in the past 3 years.**

Survey Results

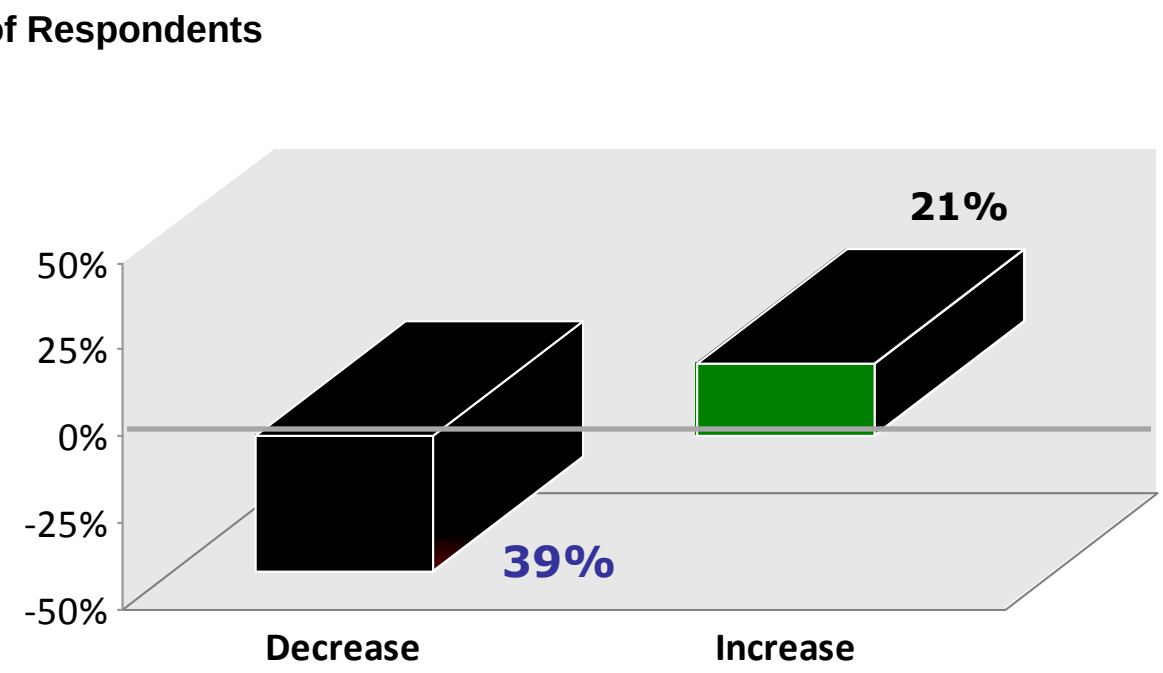
Overall Investment Trends

39% of VC firms reported decreases in their healthcare investment in the past 3 years.



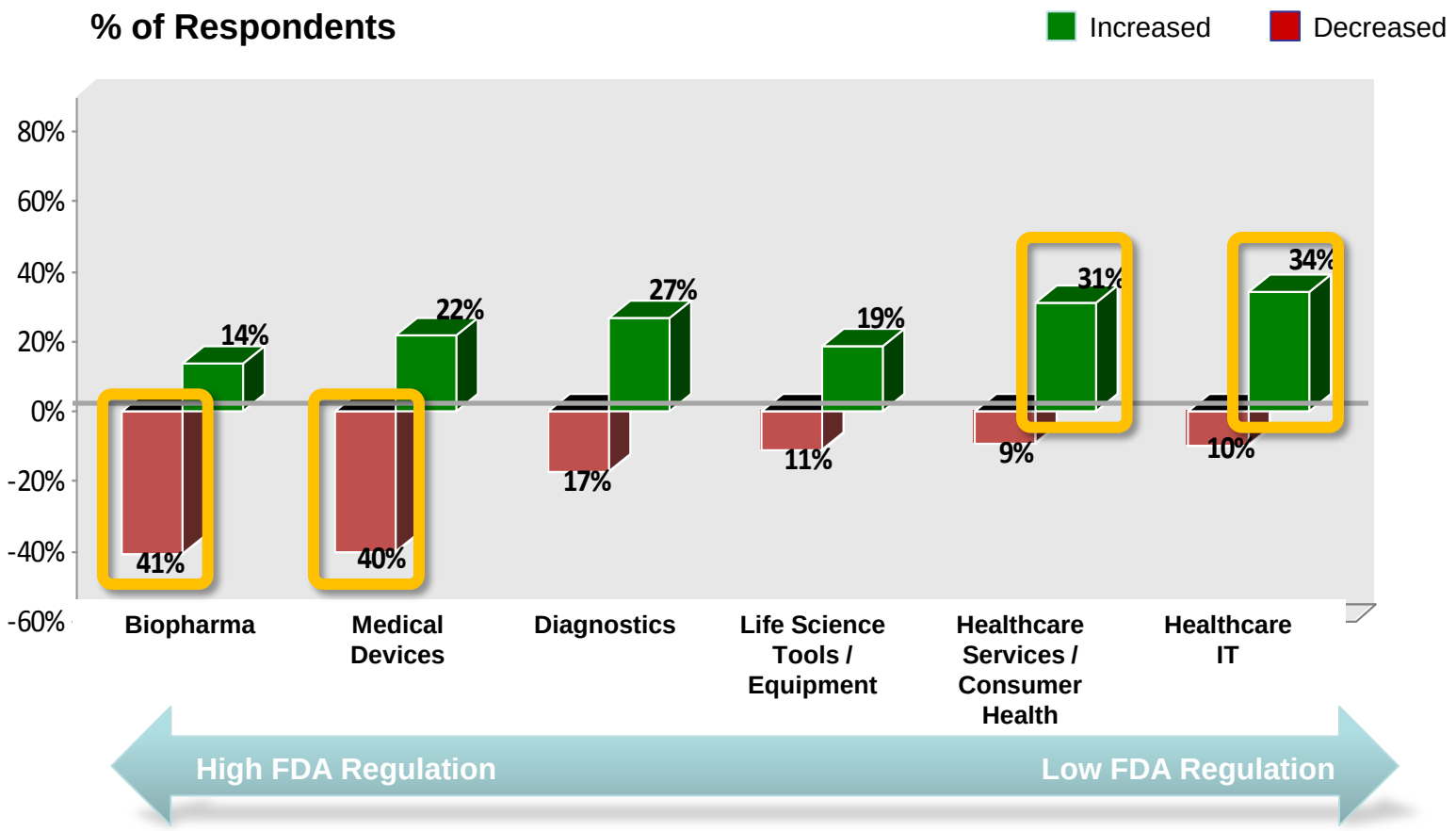
Nearly twice as many VC firms expect to decrease their healthcare investment in the next 3 years.

Next 3 Years - Expected Change in Healthcare Investments



Within healthcare, venture investment has already shifted away from Biopharma and Medical Devices.

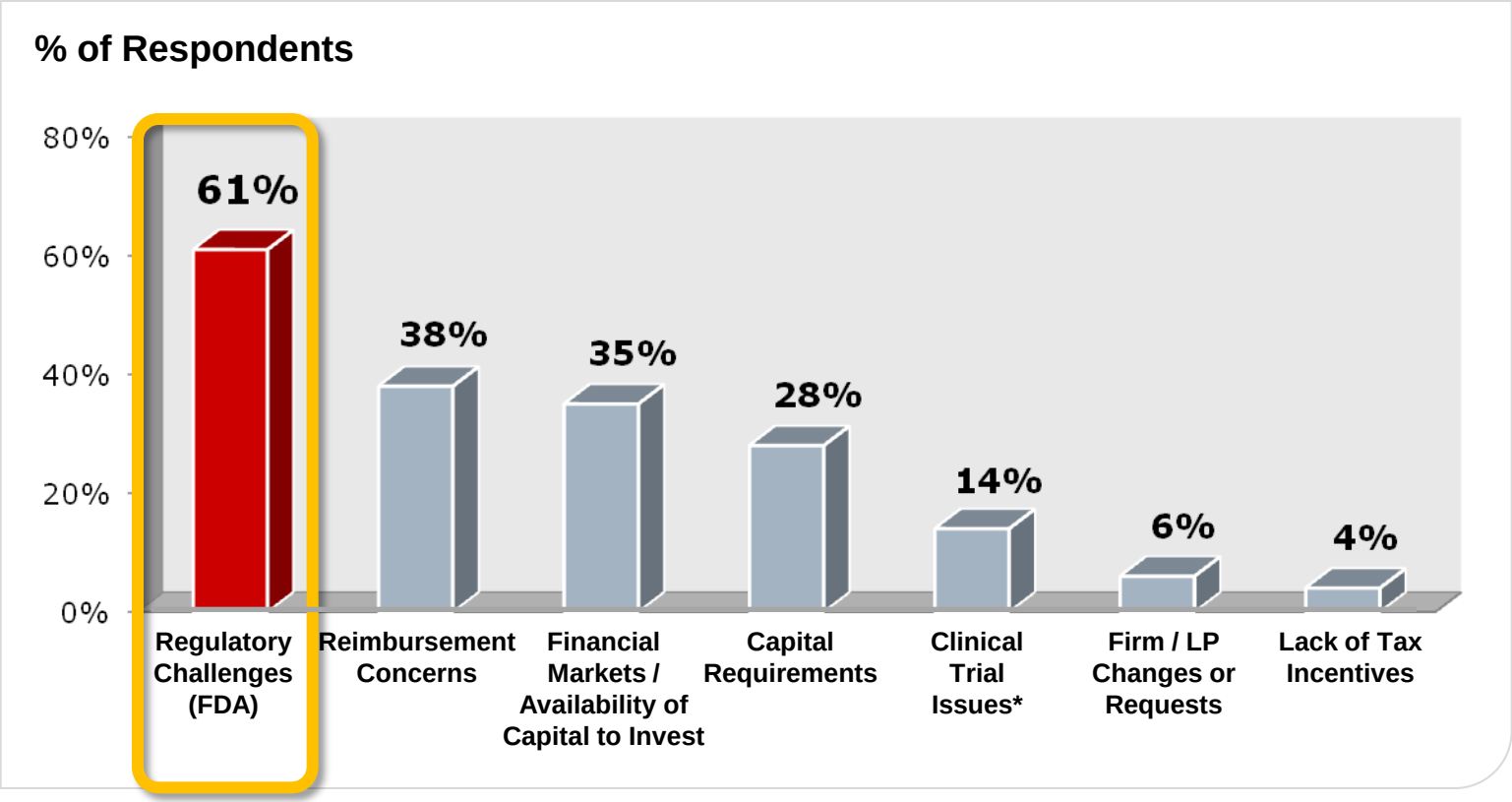
Past 3 Years - Change in Investments in Healthcare Sectors



NVCA MedIC Vital Signs Report, October 2011

FDA regulatory challenges are having the greatest impact on VC investment decisions.

Factors Cited as Having the Highest Impact on VC Investment

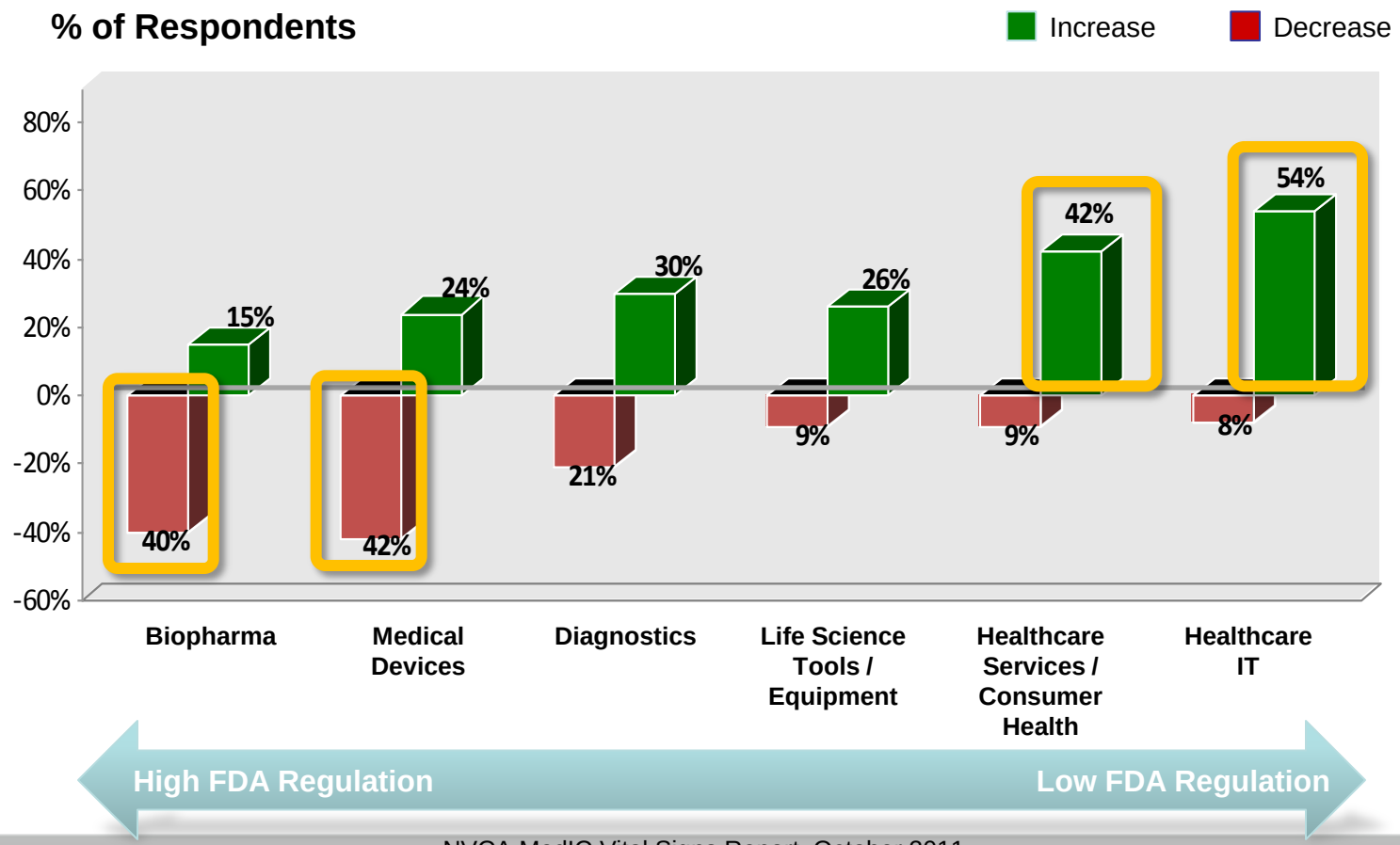


*Unrelated to Regulatory Challenges

NVCA MedIC Vital Signs Report, October 2011

VC investment in Biopharma and Medical Devices is expected to continue to suffer.

Next 3 Years - Expected Change in Investments in Healthcare Sectors



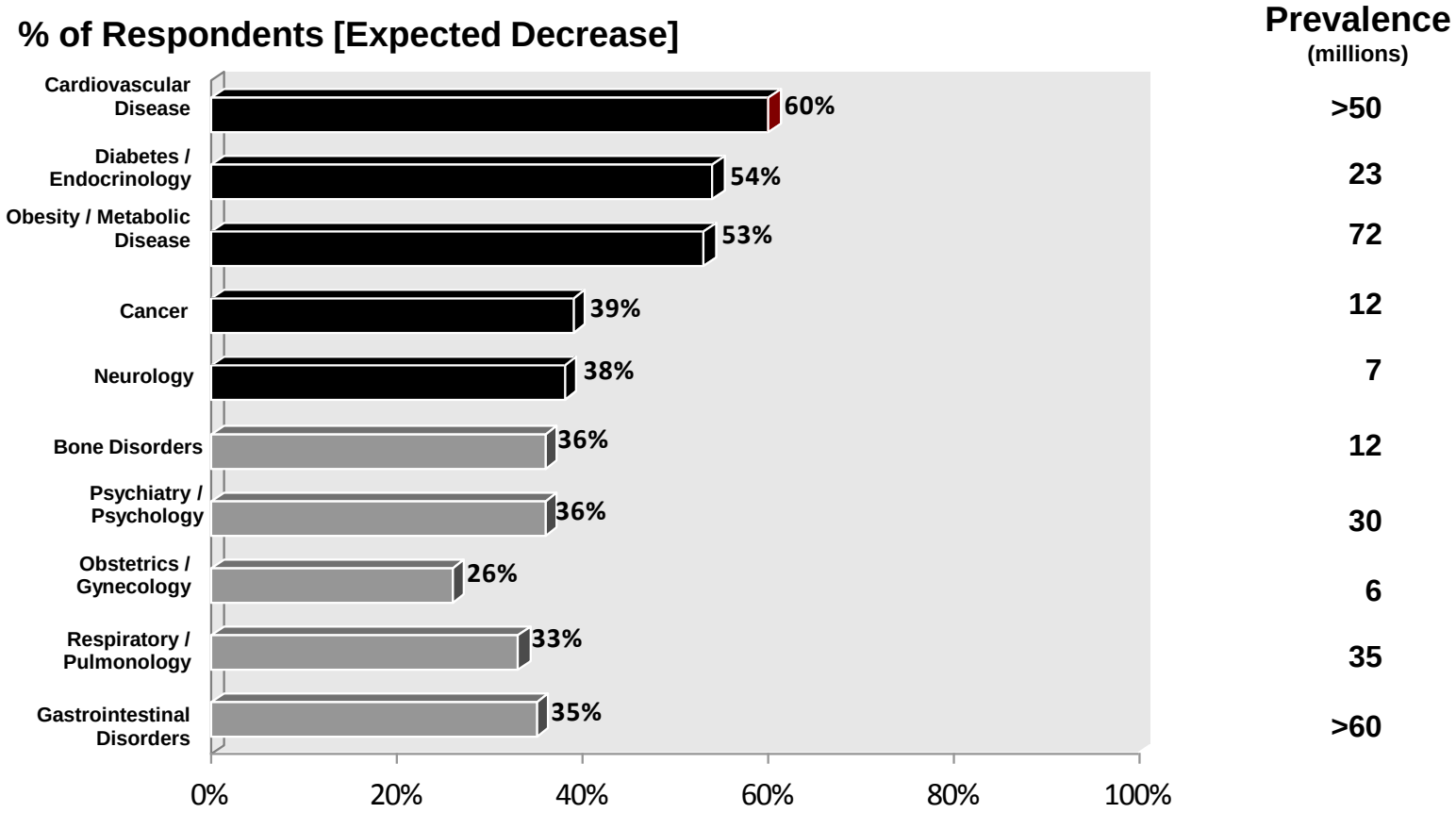
NVCA MedIC Vital Signs Report, October 2011

Survey Results

Therapeutic Area Trends

Significant decrease in VC investments expected in highly prevalent diseases.

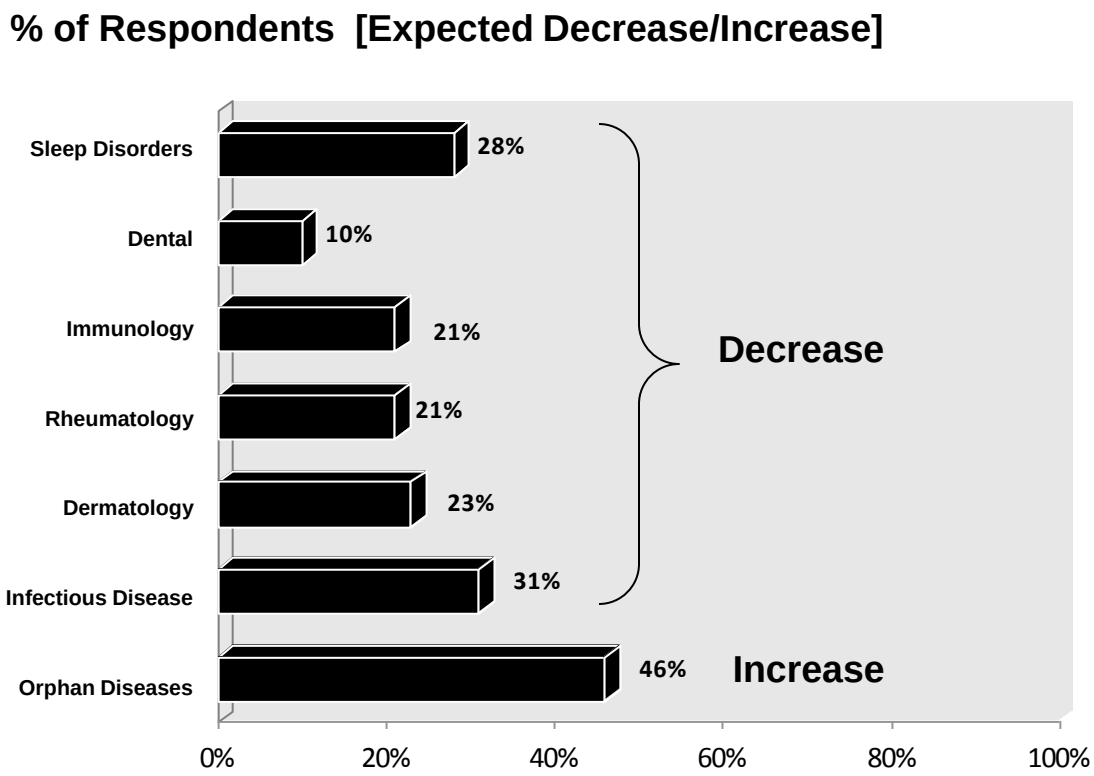
Next 3 Years - Investments in Therapeutic Areas Expected to Change



Source: CDC; NIH; American Heart Association; American Diabetes Association; Surgeon General; American Academy of Neurology; American Lung Association; US Health & Human Services; National Cancer Institute

Orphan Diseases is one of few therapeutic areas in which VC firms are expected to increase investment.

Next 3 Years - Investments in Therapeutic Areas Expected to Change



Prevalence (millions)
40
>100
23
50
>100
>28**
<0.2*

* In U.S., orphan or rare diseases is defined as a disease or condition that affects less than 200,000 people. ** Office / Hospital visits.
Source: CDC; NIH; American Academy of Dermatology; American College of Rheumatology; WHO; National Sleep Foundation.

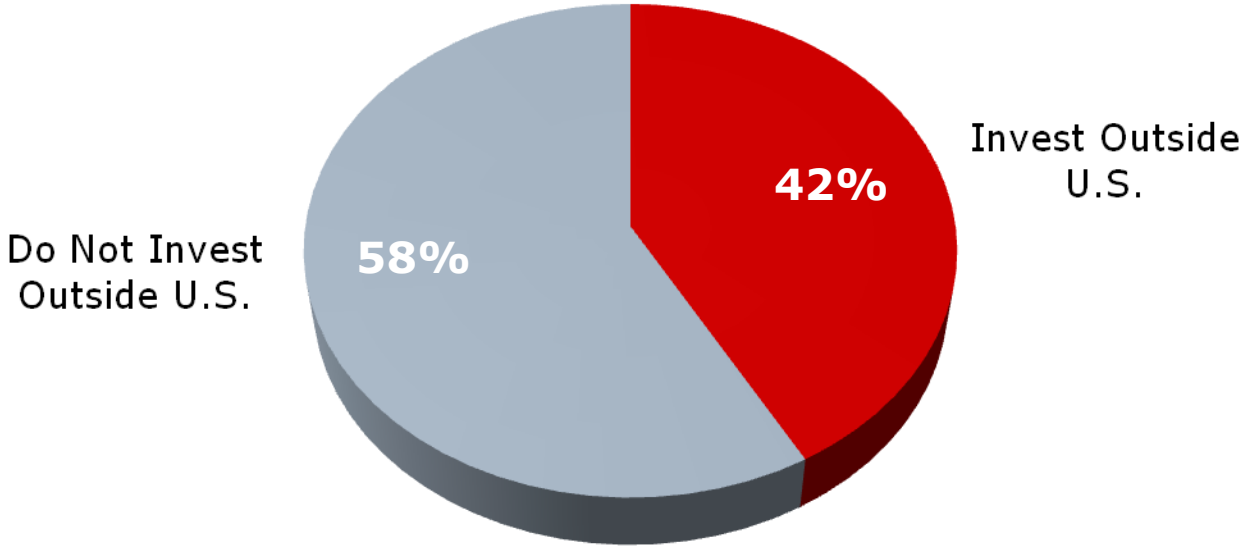
Survey Results

Global Investment Trends

Today, 42% of VC firms surveyed invest in healthcare companies outside the U.S.

Current Investment in Life Sciences Companies Outside U.S.

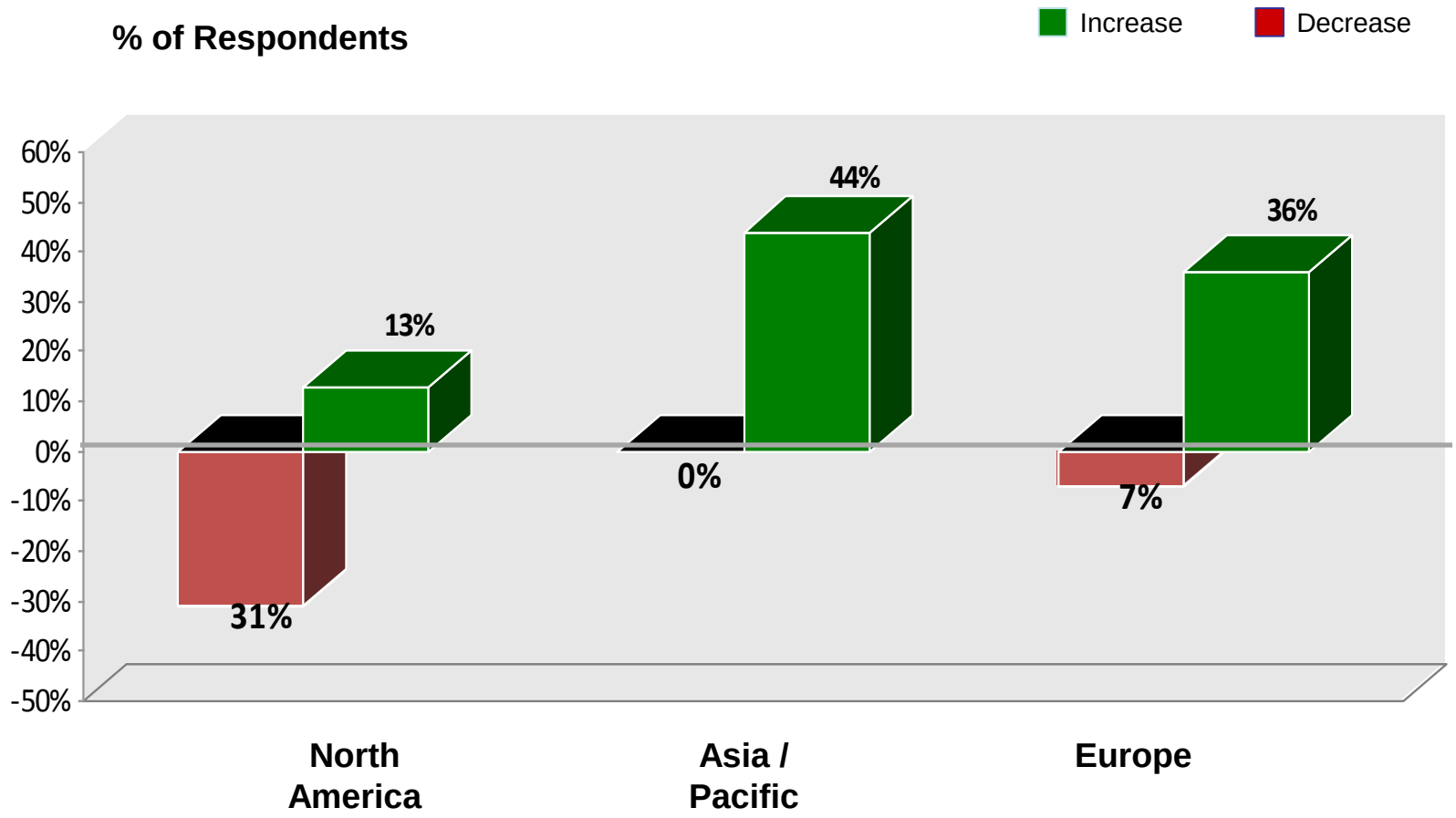
% of Respondents



NVCA MedIC Vital Signs Report, October 2011

VCs expect to decrease healthcare investment in the U.S. in favor of Asia and Europe.

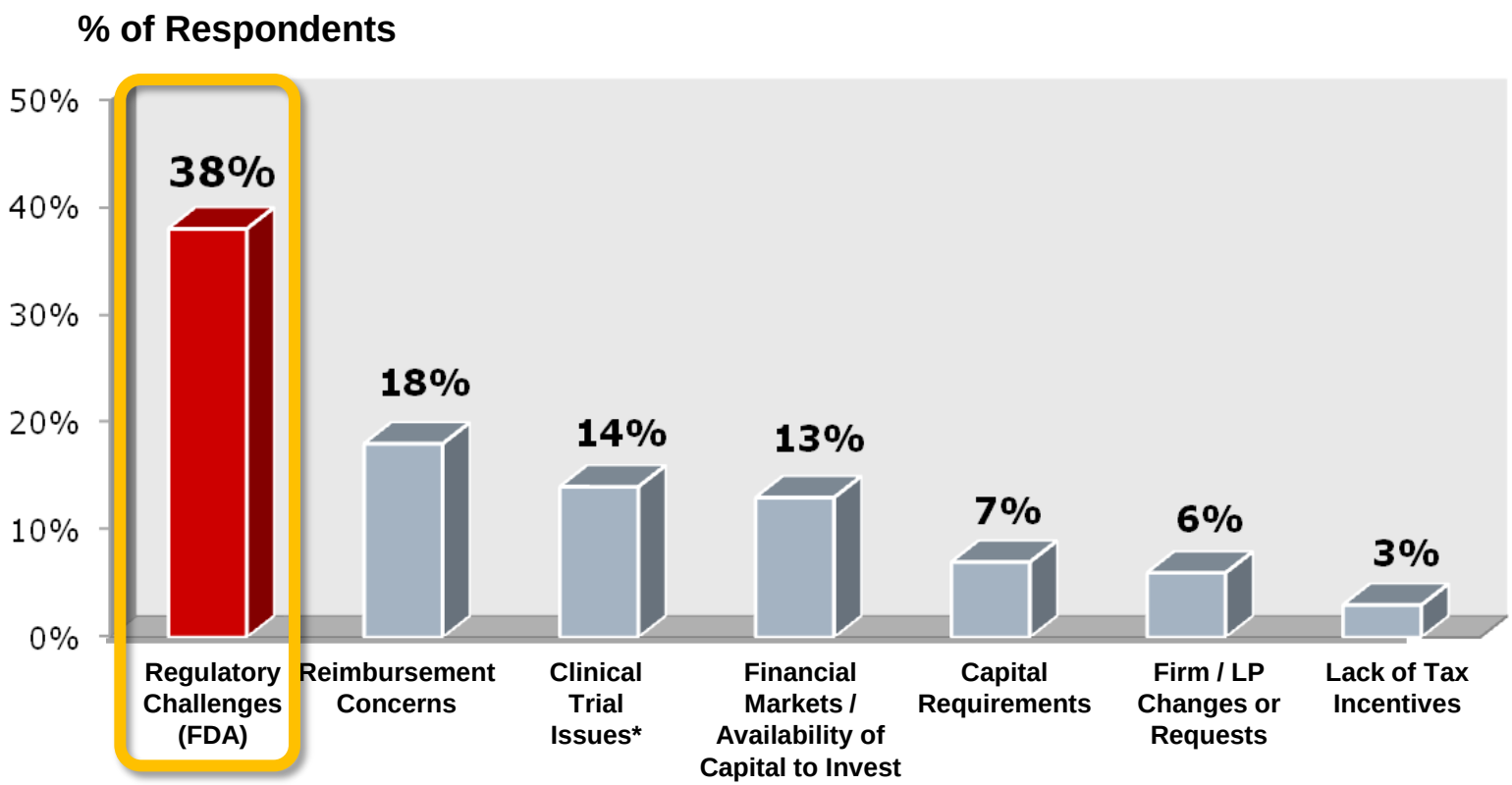
Next 3 Years - Expected Change in Healthcare Investment by Region



NVCA MedIC Vital Signs Report, October 2011

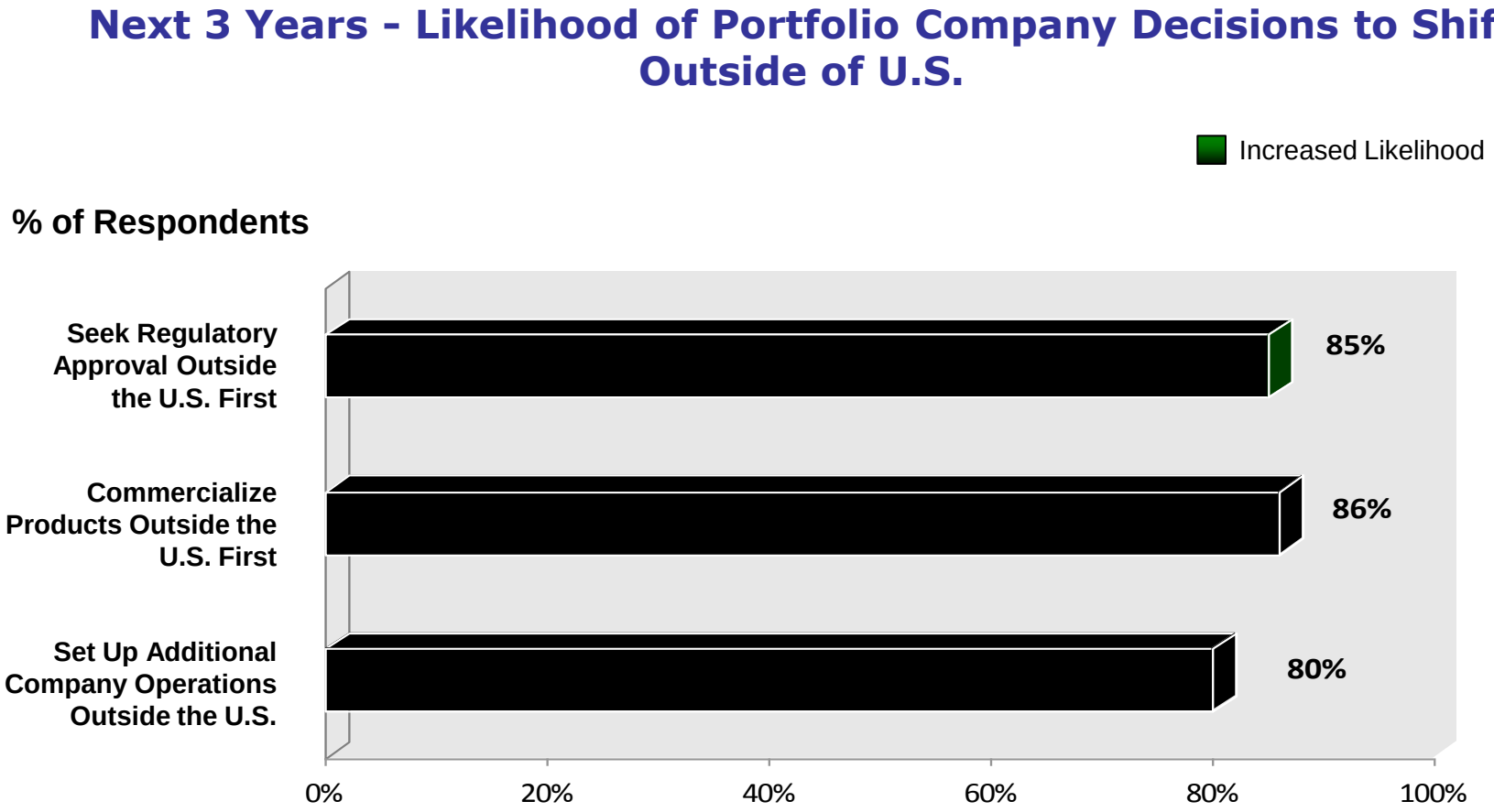
FDA regulatory challenges have the highest impact on VC firm decisions to shift investment overseas.

Factors Cited as Having the Highest Impact on Decision to Move Investment Outside of U.S.



*Unrelated to Regulatory Challenges

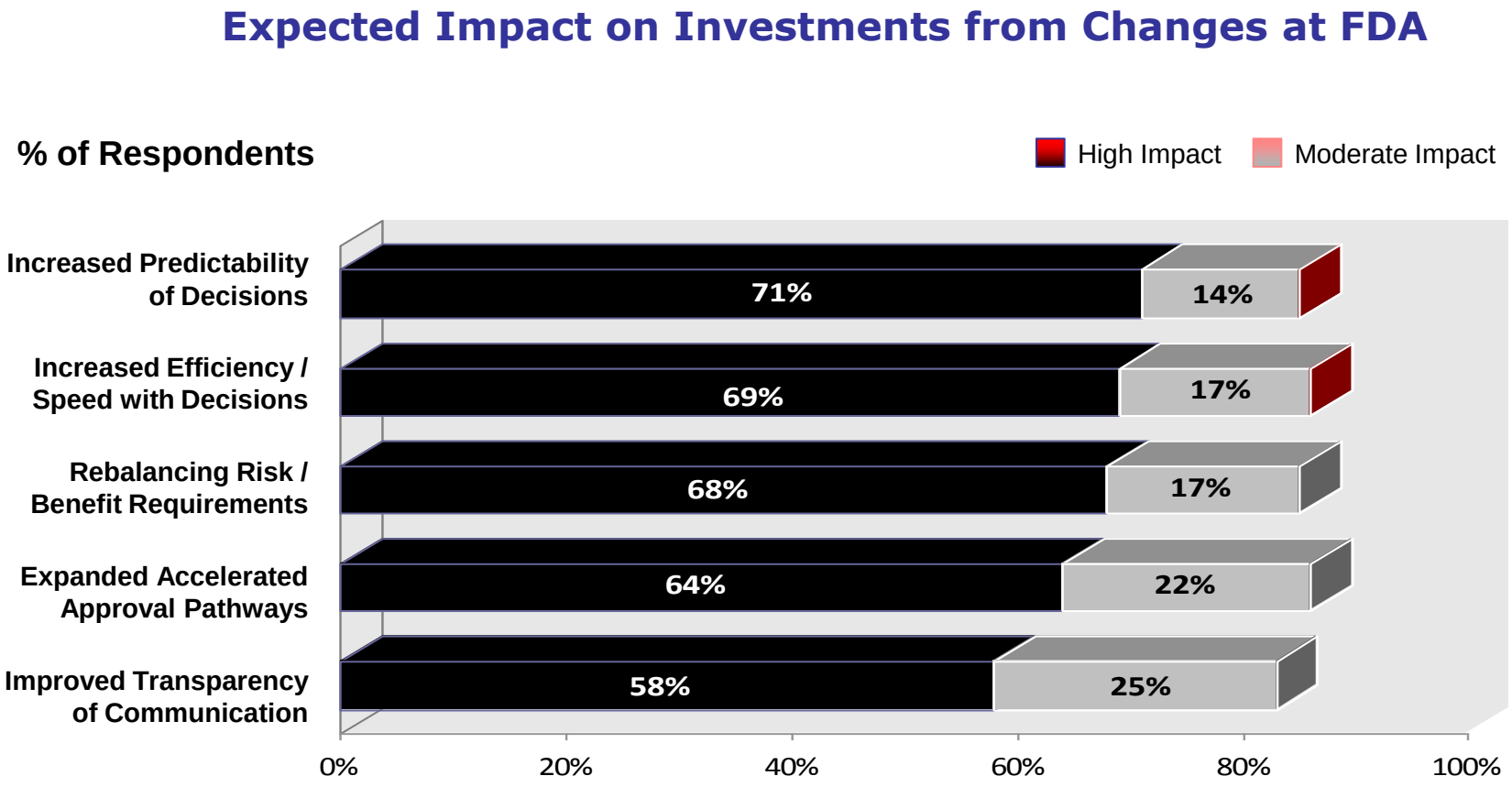
VC-backed companies are expected to increase operations outside the U.S.



Survey Results

The Need for Reform

Meaningful FDA reform is critical to reversing these trends.



Implications

If the current situation is left unaddressed, the implications to U.S. patients and the economy are significant:

- **Many promising medical therapies and technologies will not be funded and therefore will not reach the patients that need them.**
- **Those that are funded may not be brought to market in the United States first, or at all.**
- **An estimated funding loss of half a billion dollars over the next three years will cost America jobs at a time when we desperately need employment growth.**
- **The U.S. leadership position in medical innovation will be placed in further danger and economic growth with suffer.**

Call To Action

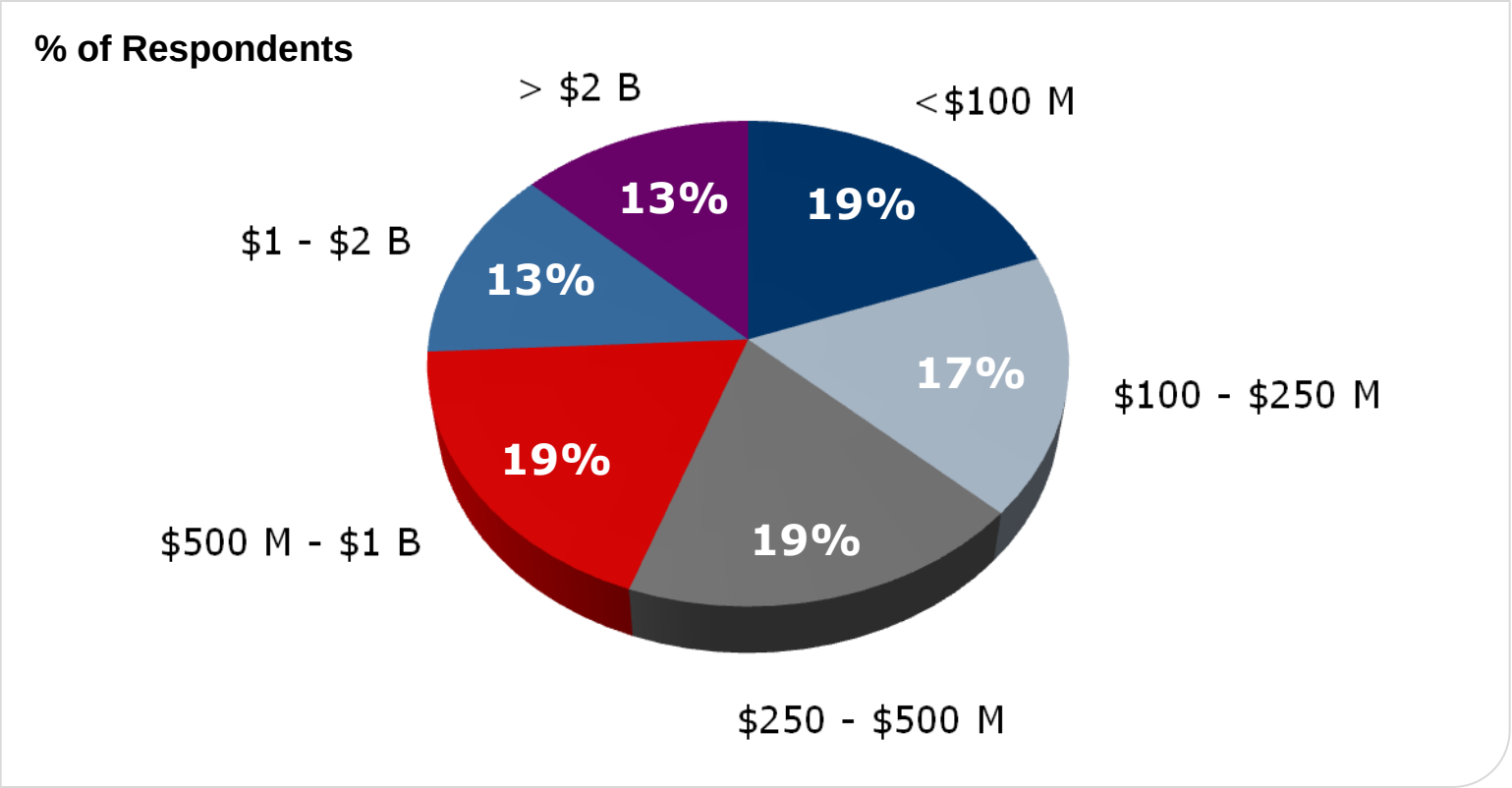
MedIC priorities include the following:

- **Rebalancing benefit-risk assessments in the drug and device approval processes to appropriately reflect the value of new therapies to patients in need;**
- **Expanding the accelerated approval pathway into a progressive approval system for drugs, diagnostics and medical devices;**
- **Ensuring conflict-of-interest policies are not hindering patient access to new treatments; and**
- **Ensuring FDA is well resourced and endowed with state-of-the-art scientific tools, clinical input, processes and procedures**

Survey Respondent Demographics

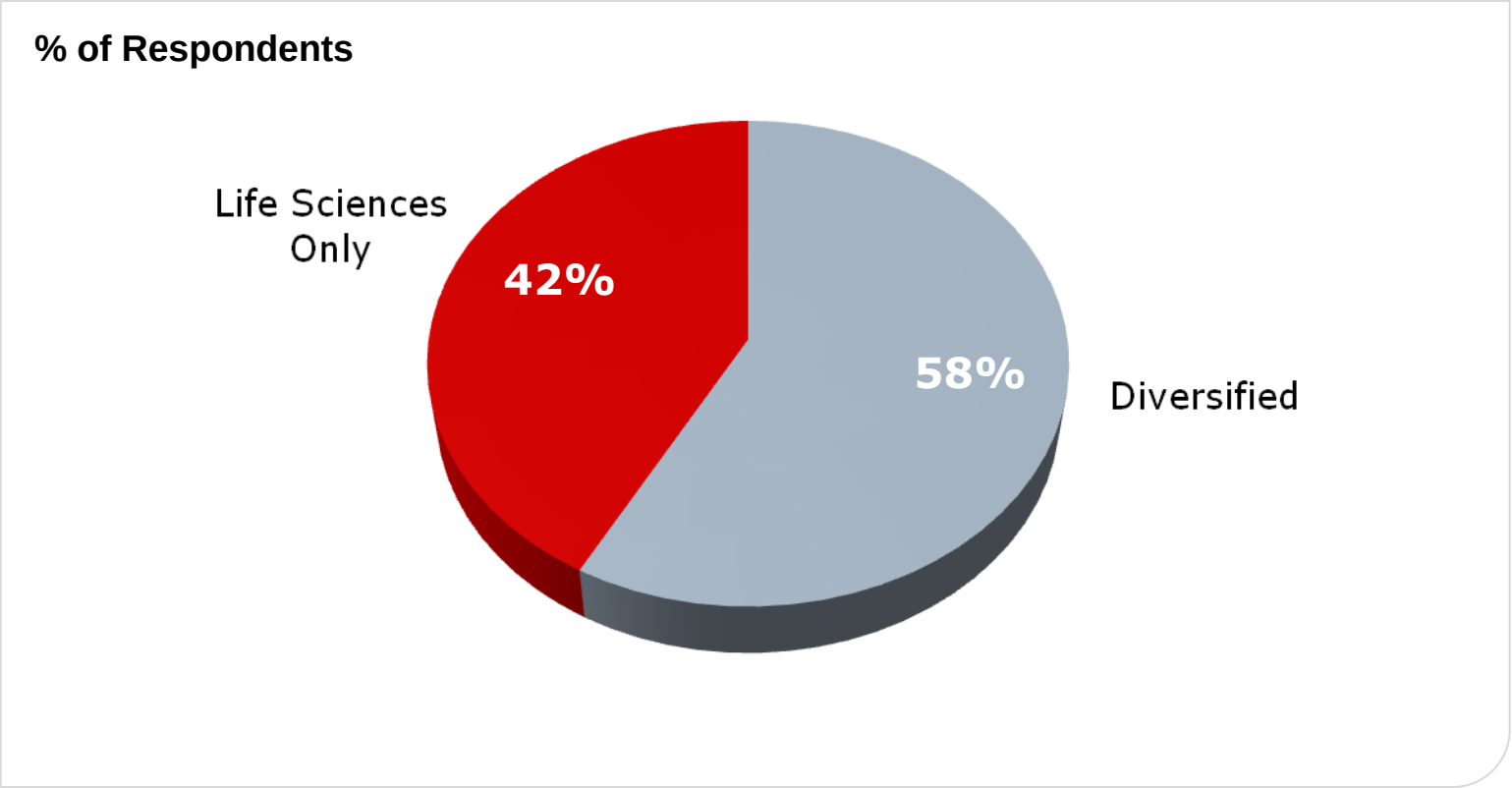
Survey respondents represent cross-section of VC firms by capital under management

Total Committed Capital Under Management

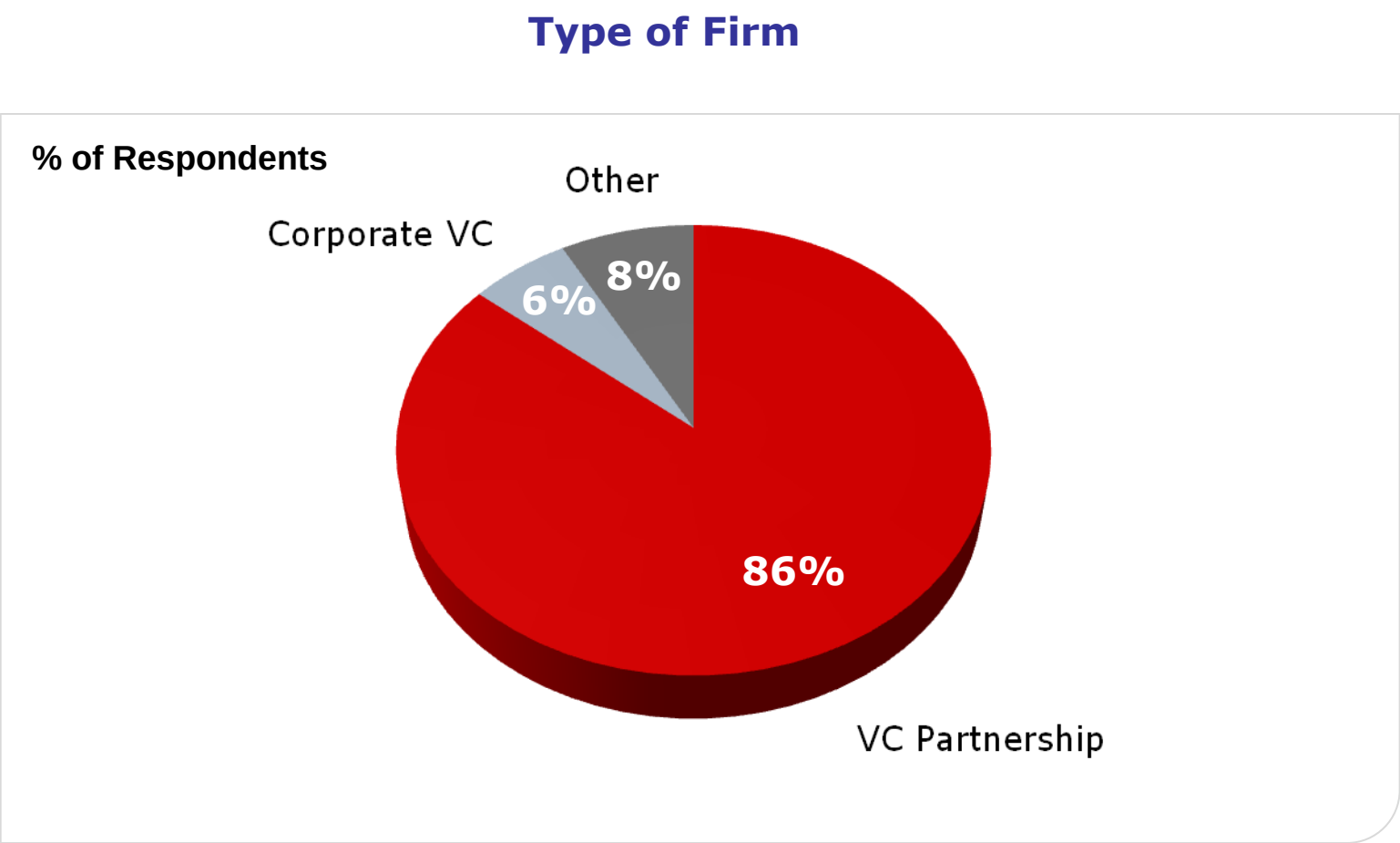


VC firms surveyed nearly even by sector focus: life sciences only vs. diversified firms

Sector Focus

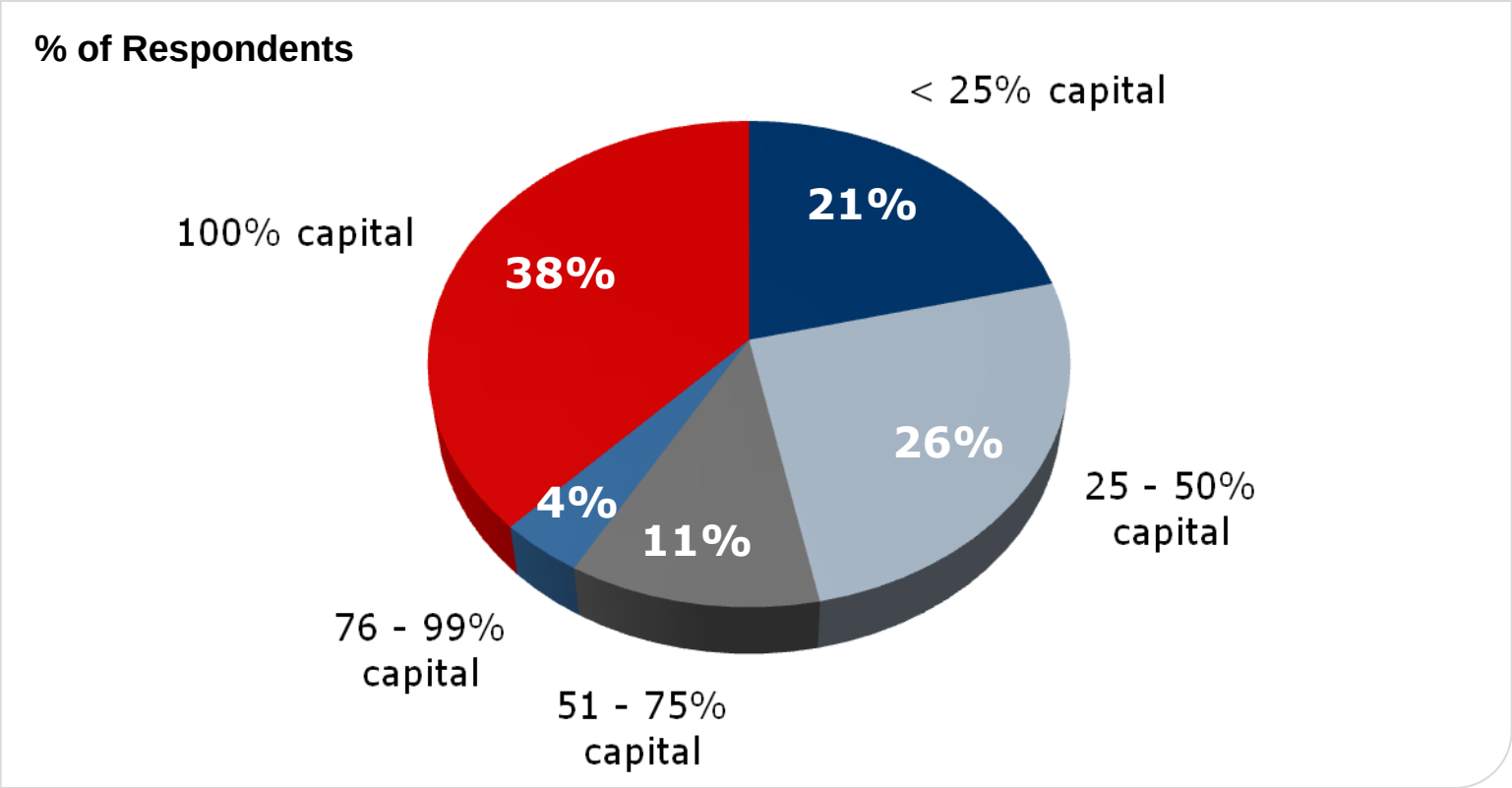


Majority of firms are private VC partnerships



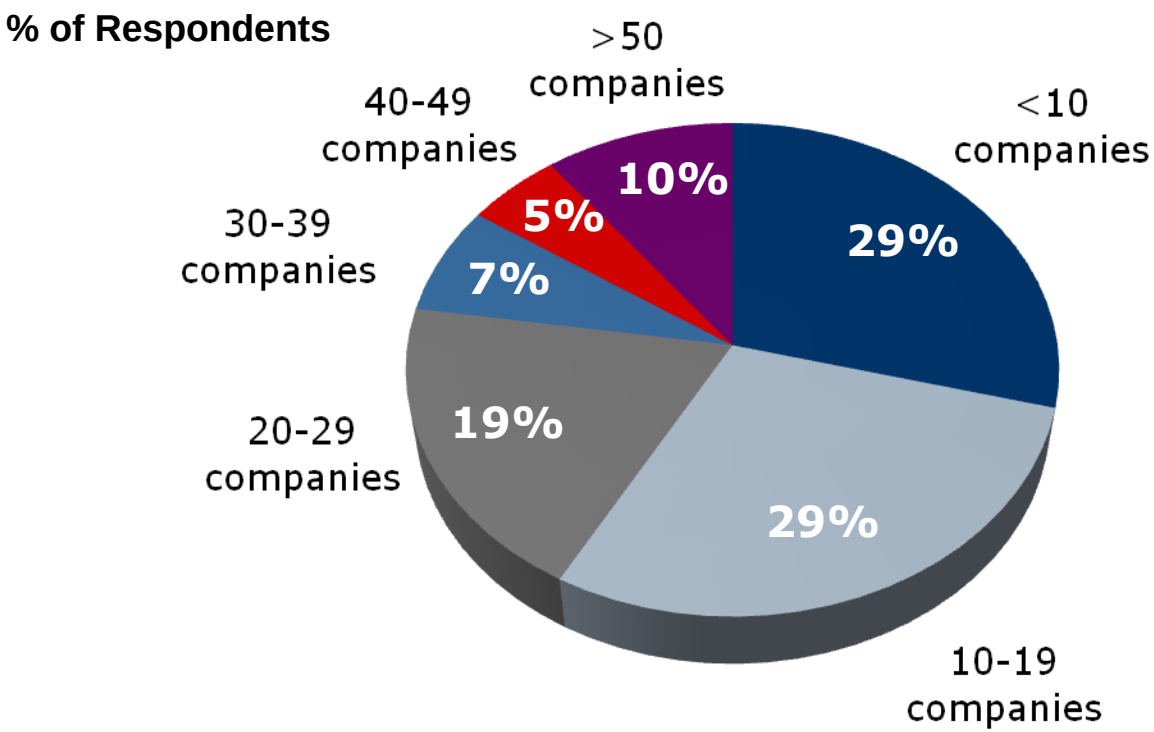
Majority of VC firms surveyed allocate >50% of their capital under management to healthcare

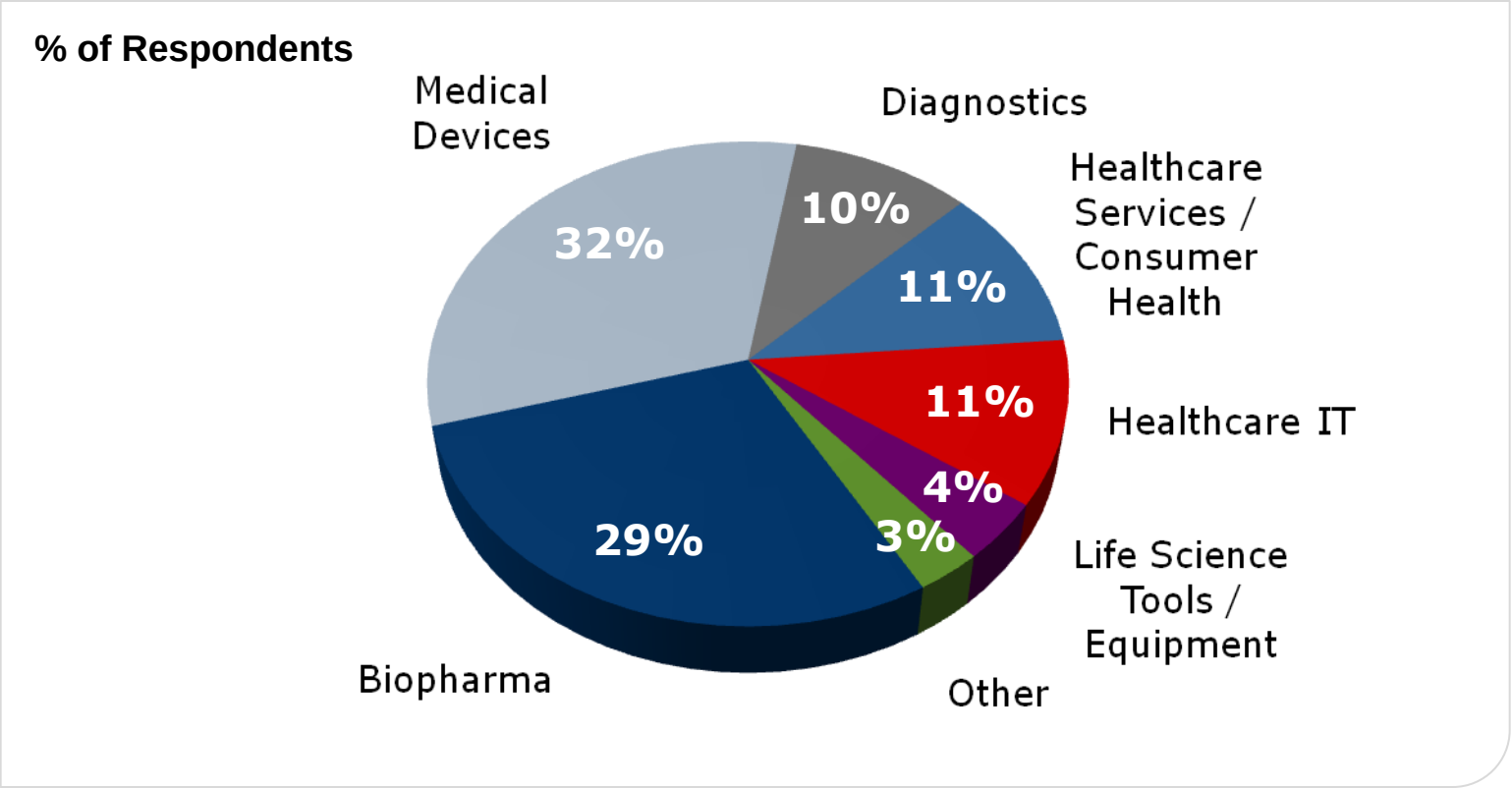
Percent of Capital Under Management Allocated to Healthcare Sectors



Most VC firms surveyed have between 10-29 active portfolio companies in healthcare

Number of Active Portfolio Companies in Healthcare



VC firms surveyed allocate most of their capital to Biopharma and Medical Devices

Average Allocation of Capital Within Healthcare