WHAT'S YOUR POLICY ON EARLY ACCESS?

CLINIGEN Consulting

THE ENVIRONMENT

CHANGING REGULATORY ENVIRONMENT

There are **increasing differences and complexities** in Early Access and Compassionate Use regulations around the world

32 States within the US have already passed Right-to-try laws

STAKEHOLDER PRESSURES

External
(Physicians, Patients, Payers, Health authorities)

Internal
(Executive level, Country Level, Business units)

RISING DEMAND FOR GLOBAL EARLY ACCESS

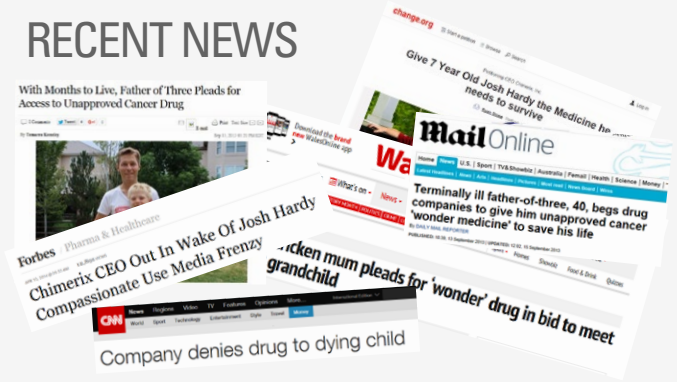
92% Increase
FDA requests for compassionate access to medicines*

62 company requests
To be part of the EMA adaptive pathways pilot**

* Source: www.fda.gov

** Source: www.ema.europa.eu

RECENT NEWS



HOW WILL YOUR ORGANIZATION PREPARE?

A Consistent and Robust Early Access Policy

- Developing a process to ensure continuity of treatment for patients exiting a clinical trial
- Providing patients with ethical, compliant, and fair access to treatments not yet commercially available
- Ensuring consistency in allowing patient access across different countries
- Future-proofing your organization from constant changes in the regulatory and political environment

Training SOPs work instructions & templates
External policy Internal policy
Strategy & Corporate Governance

BENEFITS OF EFFECTIVE POLICY DEVELOPMENT

Mitigating risks from potential legal or PR issues

Supporting a favorable image with health authorities

Building stronger and more transparent relationships with prescribing physicians and their patients

Efficiencies realized through one consistent global approach to early access across your business