



# W 10 Disclosure Guidelines for Clinical Trial Data and Milestones

For publicly traded healthcare companies, clinical trial data and milestone disclosure can present opportunities as well as challenges. By adhering to the following disclosure guidelines, you can control the message within the investment and medical communities, maximize shareholder value, and attract new investors and strategic partners.

## 1. Have a data disclosure protocol in place.

Establish a review processes for all materials (including changes to your website, social media, and public statements). Review process checklists may be helpful to guarantee adherence.

## 2. Establish appropriate timelines.

Depending on how material the information is, you will have a very limited window of opportunity to communicate the message to the Street. Work with your legal team to determine exact timing.

## 3. Ensure proper disclosure.

We recommend disclosing critical clinical trial milestones by means of a press release prior to any other verbal or written communications. Then, make sure that your message is consistent across all additional communications (investor calls, media interviews, etc.).

## 4. Maintain transparency.

Be forward about the message and do not try to "bury" the bad news in a press release. Be clear about any failures, and focus on the potential ways the company plans to move forward.

## 5. Ensure that clinical trial data is accurate and reliable.

A company is ultimately liable for all aspects of a study. It is crucial to report all relevant and correct statistics, clearly stating whether the trial has met its primary and/or secondary endpoints, along with other findings. All adverse events should be duly reported to the FDA.

## 6. Present data effectively and appropriately.

Pay particular attention to how you present data within the press release and presentation slides. In case of a positive data readout, highlight in the headline of your press release the fact that the trial results are actually positive, since most analysts and investors will initially assume the data is gray or poor if the headline is neutral.

## 7. Be particularly careful as to how you disclose "top line" results.

Disclosure of top line data is particularly challenging, because you cannot yet disclose the underlying data. Carefully consider whether these results absolutely must be disclosed at this point in time and what the messaging around these results should be.

## 8. Increase visibility.

If the data is positive, it can be beneficial to conduct an investor call to discuss the data and answer main questions from analysts and investors.

## 9. Consider reporting at conferences.

Timing of data readout can be relatively predictable, so it can be beneficial to plan to report the full set of data at a medical or scientific conference.

## 10. Publish peer-reviewed data.

Publication in peer-reviewed scientific journals is currently the primary method for sharing clinical trial data with the scientific and medical communities, as well as the public through media coverage of the findings.

A healthcare company faces a range of challenges as it guides its products through clinical trials. For more guidance on disclosure or your overall investor relations strategy, [contact us](#).