

## WHAT IS THE DIGNITY STUDY?

The **Dignity study** is a medical research study investigating a potential new medication for urinary incontinence due to overactive bladder in people with multiple sclerosis or a spinal cord injury.

## BENEFITS FOR DIGNITY STUDY PARTICIPANTS

There are several good reasons why you should consider getting involved in the **Dignity study**:

- You will be taking part in a clinical study of an experimental medication that could control your urinary incontinence episodes and help improve the lives of others like you
- The investigator and site will ensure that you are monitored and looked after; they will listen to you and discuss any questions you may have

All investigational study medication, medical exams, and lab tests will be provided at no charge.

## IS THE DIGNITY STUDY RIGHT FOR YOU?

If you are interested in taking part in the **Dignity study** and would like further information, you can:

🌐 visit [www.DignityStudy.com](http://www.DignityStudy.com)

📞 call **1-888-61-STUDY (1-888-617-8839)**

Don't forget, you are under no obligation to take part and you can stop at any time.

**YOU** can make a difference by getting involved in medical research that could shape the future treatment of urinary incontinence in patients with multiple sclerosis or spinal cord injury.

The protocol for the Dignity study has undergone the appropriate review by regulatory authorities and ethics committees.

**Do you have overactive bladder** due to multiple sclerosis or spinal cord injury?



We want to help you, and others like you.

To do that, **we need your help.**



## DO YOU QUALIFY FOR THE DIGNITY STUDY?

Below is a list of the main requirements for qualifying for the **Dignity study**. If you are considering joining the **Dignity study** and can check **all** the boxes, we would like to hear from you.

- Age between 18 and 80 years old, and weight at least 50 kg (110 lb)
- One of the following conditions:
  - Spinal cord injury** either:
    - at the 1<sup>st</sup> thoracic (chest) spinal bone or below occurring at least 6 months ago or
    - at the 5<sup>th</sup> through 8<sup>th</sup> cervical (neck) spinal bone occurring at least 12 months before or
  - Multiple sclerosis:**
    - stable with no significant changes in therapy or worsening/improvement for at least 3 months
    - and either with a physical disability ranging from none to needing assistance to walk more than 20 meters without resting,
    - or essentially restricted to a wheelchair but with effective use of arms
- Urinary incontinence as result of an overactive bladder for a period of at least 3 months

- Willingness to use intermittent catheterization

There are also factors that may exclude you and these will be explained to you by your treating physician.

## WHAT DOES PARTICIPATION IN THE DIGNITY STUDY INVOLVE?

If you decide to take part in the **Dignity study**, there are a few key steps you will be asked to follow:

- Initial visit to your physician for a physical examination and to discuss your medical history
- Second visit to your physician to receive the study medication for the first time, which may be the medication under investigation or a placebo (looks the same as the study medication but has no active ingredient) followed by periodic assessments by phone or during an office visit
- Opportunity to re-qualify after 12 weeks to receive the medication under investigation – this means everyone will receive the study medication at some point during the study, if not right from the start

## REVIEW AND CONFIDENTIALITY

The **Dignity study** is regulated by US and international laws that govern medical research and protect the welfare of participants.

The study will involve collecting some personal information about you. However, it will be stored securely and even when the results of the trial are published, your name will not be made public.

The physician will not enter you into the study until you are clear about what is involved and have given your written consent to take part.

You can stop participating in the study at any time without having to give a reason.

