

FOR ADULTS, CHILDREN, AND INFANTS WITH SPINAL MUSCULAR ATROPHY (SMA)



Individual results may vary based on several factors, including severity of disease, initiation of treatment, and duration of therapy.* All individuals depicted in this brochure are real patients or caregivers who have been compensated for their time.

WHAT IS SPINRAZA?

SPINRAZA® (nusinersen) is a prescription medicine used to treat spinal muscular atrophy (SMA) in pediatric and adult patients.

SELECTED IMPORTANT SAFETY INFORMATION

Increased risk of bleeding complications has been observed after administration of similar medicines. Your healthcare provider should perform blood tests before you start treatment with SPINRAZA and before each dose to monitor for signs of these risks. Seek medical attention if unexpected bleeding occurs.

Please see additional Important Safety Information on page 27 and full Prescribing Information.

*Pivotal trials did not include adult patients with spinal muscular atrophy (SMA).

WELCOME TO SPINRAZA

FIND YOUR SPIN ON SMA

As the first FDA-approved treatment for spinal muscular atrophy (SMA), SPINRAZA® (nusinersen) has helped many of those living with this disease. Everyone's experience may be different; wherever you are on your SMA journey, SPINRAZA is here for you. So, whether you're just **starting treatment** with SPINRAZA, **restarting treatment** on SPINRAZA, or **simply staying on course**, learn about the latest data on the treatment that is helping so many people with SMA.

LUCIANO ON SPINRAZA

Individual results may vary based on several factors, including severity of disease, initiation of therapy, and duration of therapy.



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Discover the data
on early-onset SMA

LEARN MORE AT [SPINRAZA.com](https://www.spinraza.com)



SELECTED IMPORTANT SAFETY INFORMATION

Increased risk of kidney damage, including potentially fatal acute inflammation of the kidney, has been observed after administration of similar medicines. Your healthcare provider should perform urine testing before you start treatment with SPINRAZA and before each dose to monitor for signs of this risk.

Please see additional [Important Safety Information](#) on page 27 and full [Prescribing Information](#).

FACTS ABOUT SMA

People living with SMA will experience motor function loss throughout their lives



Muscles need signals from the CNS

SMA is a genetic disorder caused by insufficient levels of survival motor neuron (SMN) protein, a protein that is needed for motor neurons to survive. Motor neurons send signals to muscles from the central nervous system (CNS).



SMN1 is mutated in SMA

Without sufficient SMN protein, motor neurons die off. With no signals from the CNS, muscles get weaker and weaker.



SMA=insufficient SMN protein

Natural history shows that all people living with SMA will experience motor function loss throughout their lives. For people living with SMA, these losses may become more noticeable with age.

It is difficult to know when you will experience motor function loss

The rate of motor function loss varies from person to person, and it is difficult to predict when someone living with SMA will experience motor function loss. In adults, children, and infants, muscle loss is permanent and can happen quickly, so it is important to manage your condition as soon as possible. Those living with SMA may experience periods where motor function appears stable but will still experience motor function loss over time. Below are some key facts about SMA disease progression:

- **Motor function loss can become more obvious over time**

It can be hard to notice motor function loss with annual checkups because it may be happening slowly. But that doesn't mean it isn't happening. Such loss becomes more noticeable as it continues over time

- **Type and age may not always be predictors of motor function loss**

Because everyone experiences SMA differently, it is difficult to predict when and how rapidly motor function loss will happen

Be sure to talk to your doctor about changes in your motor function.



Genetic testing can confirm an SMA diagnosis.

Today, newborn screening is available in all 50 states. Genetic testing is recommended to confirm the mutation for infants and is also accessible for adults.

Ask your healthcare provider (HCP) for more information about genetic testing.

Please see [Important Safety Information](#) on page 27 and full [Prescribing Information](#).

ABOUT SPINRAZA



SPINRAZA was the first FDA-approved therapy for SMA

The legacy of SPINRAZA runs deep, with nearly a decade of clinical studies, substantial real-world data, and more than 14K people treated worldwide.*

FROM 1 DAY TO
85 YEARS OLD^{†‡}

there's someone from almost every age group who has taken SPINRAZA

5300+
ADULTS
have been treated with SPINRAZA worldwide**

9000+
CHILDREN
have been treated with SPINRAZA worldwide*



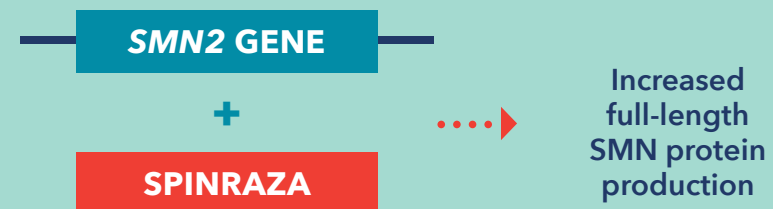
SPINRAZA is delivered directly to the CSF at the site of motor neuron loss

People with SMA can't generate enough full-length SMN protein, the protein their motor neurons need to function. That's where SPINRAZA can help. It is delivered to the cerebrospinal fluid (CSF), the area surrounding the spinal cord, allowing it to be distributed to the target tissues. While you continue treatment, SPINRAZA helps your body increase the production of SMN protein.

SPINRAZA targets the underlying cause of muscle weakness in SMA—helping muscles maintain and gain function

People with SMA can't make enough SMN protein because they have a mutated or missing survival motor neuron 1 (*SMN1*) gene. The gene they do have, *SMN2*, does not produce enough of the SMN protein that is needed for motor neurons to survive.

HOW SPINRAZA WORKS



SELECTED IMPORTANT SAFETY INFORMATION

Increased risk of kidney damage, including potentially fatal acute inflammation of the kidney, has been observed after administration of similar medicines. Your healthcare provider should perform urine testing before you start treatment with SPINRAZA and before each dose to monitor for signs of this risk.

Please see additional [Important Safety Information on page 27](#) and full [Prescribing Information](#).

*Based on commercial patients and early access patients receiving treatment with SPINRAZA as of June 2024.
 †Based on patients receiving treatment with SPINRAZA in the US as of May 2024.
 **SPINRAZA (12 mg) clinical studies included patients from 3 days to 16 years of age at first dose and did not include sufficient numbers of subjects aged 65 and older to determine whether they respond differently from younger patients. Pivotal studies did not include adult patients.




STUDY OVERVIEW



SPINRAZA is backed by a decade of data from multiple studies in SMA

SPINRAZA has been studied for nearly a decade in the longest SMA clinical development program to date.

Clinical Study Overview

	 SPINRAZA clinical studies used to grant FDA-approval		 real-world evidence*	
PRESYMPTOMATIC SMA	EARLY-ONSET SMA	LATER-ONSET SMA	LATER-ONSET SMA	
Infants ≤6 weeks	Infants ≤7 months	Children 2 to 9 years	Pediatric & Adults 5 to 66 years	Teens & Adults 16 to 71 years
NURTURE	ENDEAR	CHERISH	ŁUSAKOWSKA	SMArtCARE
Supportive study that examined survival without respiratory intervention in 25 infants who have yet to show symptoms of SMA	Clinical study that researched survival without permanent ventilation and motor milestone response in 121 children with early-onset SMA	Clinical study that investigated changes in motor function in 126 nonambulatory children with later-onset SMA	Real-world study that observed changes in motor function in 120 children and adults for up to 30 months	Real-world study that observed changes in motor function in 237 teens and adults for up to 38 months

*These types of studies provide further information to add to SPINRAZA clinical studies across a broad range of ages and SMA severity.

SELECTED IMPORTANT SAFETY INFORMATION

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These are not all of the possible side effects of SPINRAZA. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at **1-800-FDA-1088**.





Before taking SPINRAZA, tell your healthcare provider if you are pregnant or plan to become pregnant.

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Measurements used in SPINRAZA studies

SPINRAZA studies use motor function assessments to track improvements, but they can be complex or unfamiliar. Definitions for all motor function assessments in this brochure are shown here.

Motor Function Scales:

			
HINE-2 Up to 2 years old	RULM 30 months to 27 years	HFMS 2 to 45 years	6MWT 4 to 48 years
Section 2 of the Hammersmith Infant Neurological Examination is used to assess improvements in motor function. The scale includes activities such as head control, independent sitting, and standing. Each activity has a maximum score between 2-4 points, with a total maximum score of 26	The Revised Upper Limb Module is a scale used to measure upper limb strength and function. It measures how well someone can do daily tasks, like pushing buttons and opening containers. Each item is scored from 0 to 2, with a maximum score of 37	The Hammersmith Functional Motor Scale-Expanded is an SMA-specific scale used to measure how well someone can do daily tasks, like lifting their head, sitting, and stair climbing. Each item is scored from 0 to 2, with a maximum score of 66	The 6-Minute Walk Test is used to measure how far a person can walk in 6 minutes

- The **World Health Organization (WHO) motor milestones** are a set of 6 milestones—such as sitting without support, hands-and-knees crawling, and walking alone—that healthy children are expected to achieve by 2 years of age
- The **Patient Global Impression-Improvement (PGI-I)** is a survey that asks participants to assess their treatment, ranging from very much improved to very much worse
- The **Children’s Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)** measures 16 motor functions in infants with SMA Type 1

ENDEAR CLINICAL STUDY



SPINRAZA delivered powerful survival results and motor function improvement for children with SMA

- **Who:** 121 children 7 months of age and younger with SMA Type 1 (80 children were treated with SPINRAZA versus 41 who were given a placebo)
- **Study time:** 13 months
- **Safety:** The most common side effects were lower respiratory infection (55%) and constipation (35%). Serious adverse reactions of atelectasis (collapsed lung) were more frequent in the SPINRAZA-treated group (18%) than in the control group (10%)

Primary outcomes:

- Time to death or use of permanent assisted ventilation
- The proportion of children who had an improvement in motor milestones, according to HINE-2
- On average, **those with SMA Type 1 showed improvements in motor milestones** that are rarely, if ever, achieved in untreated children

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At 13 months, **51% of children treated with SPINRAZA showed improvement*** in motor milestones versus 0% in the untreated control group.

Motor milestones included:



Head control



Rolling



Crawling



Walking



Standing



Independent sitting

*According to HINE-2, a responder was defined as a child who has had at least a 2-point increase in ability to kick, or at least a 1-point increase in categories such as head control, rolling, sitting, crawling, standing, or walking, and improvement in more categories of motor milestones than worsening.

47%

reduced risk of mortality
or permanent ventilation
in SPINRAZA group versus
the untreated group

&

63%

reduced risk of mortality
in the SPINRAZA group
versus the untreated group

CHERISH CLINICAL STUDY

People with later-onset SMA treated with SPINRAZA showed significant improvements in motor function

- **Who:** 126 individuals ages 2 to 9 years with later-onset SMA
- **Study time:** 15 months
- **Primary outcome:** Changes in motor function, measured with HFMSE
- **Secondary outcomes:** Changes in upper limb function, measured with RULM, and percentage of individuals who had a clinically meaningful improvement (3 or more points) from baseline in HFMSE score
- **Limitation:** The dosing schedule was different from the approved SPINRAZA dosing schedule
- **Safety:** The most common side effects were fever (43%), headache (29%), vomiting (29%), and back pain (25%)



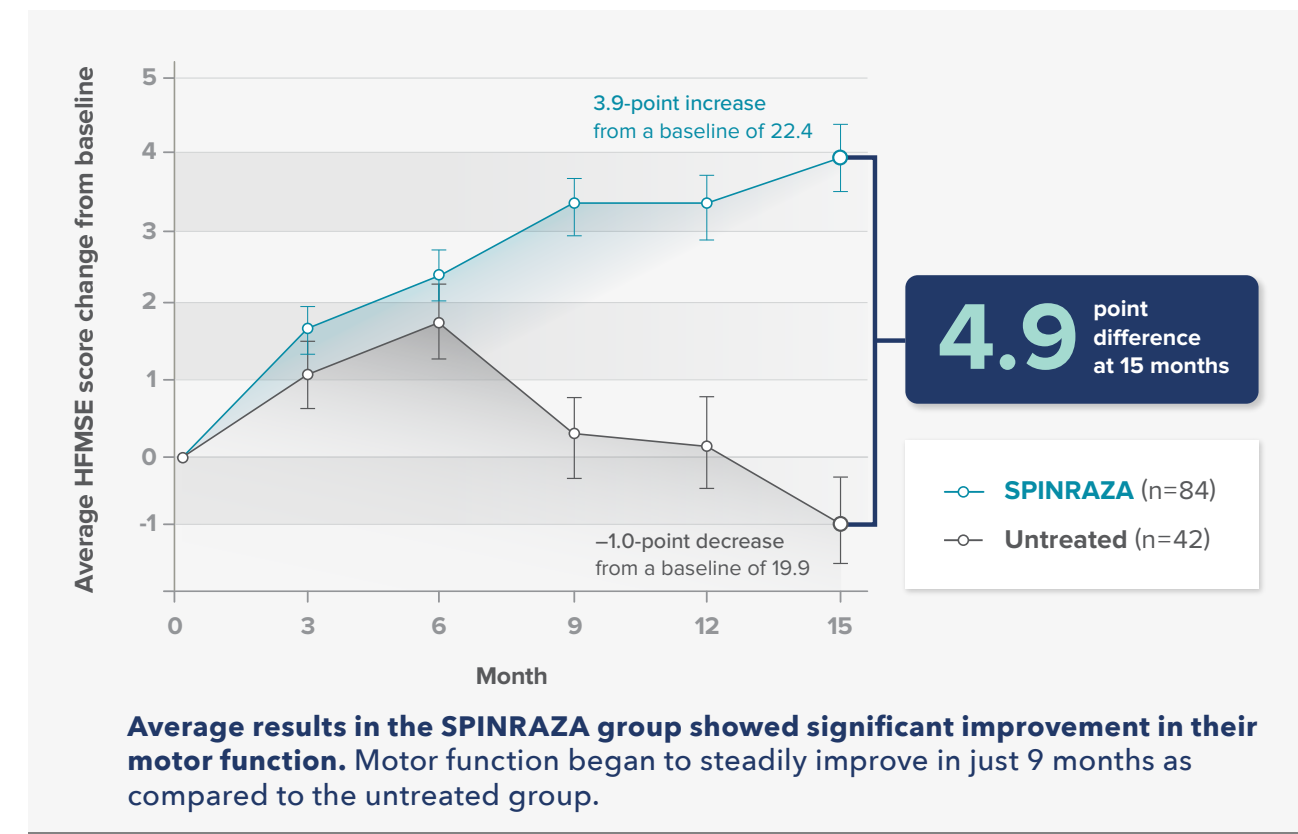
RUBY
ON SPINRAZA

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Primary outcome: average change from baseline in HFMSE total score at 15 months versus untreated individuals



SELECTED IMPORTANT SAFETY INFORMATION

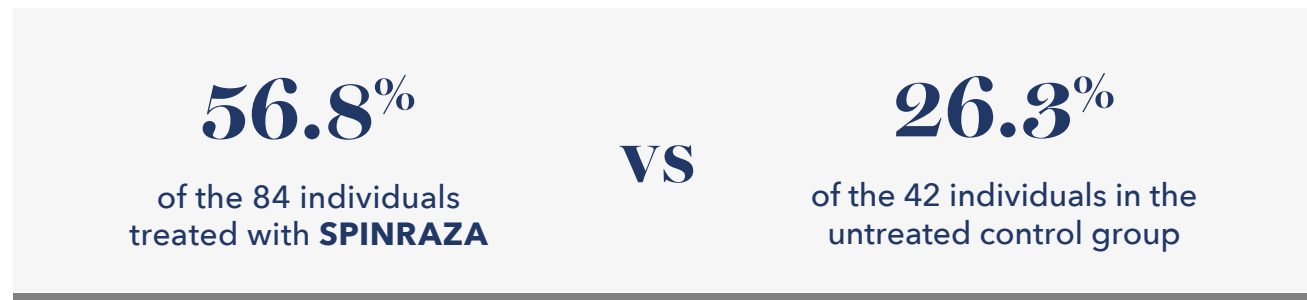
The most common side effects of SPINRAZA include lower respiratory infection, fever, constipation, headache, vomiting, back pain, and post-lumbar puncture syndrome.

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CHERISH CLINICAL STUDY

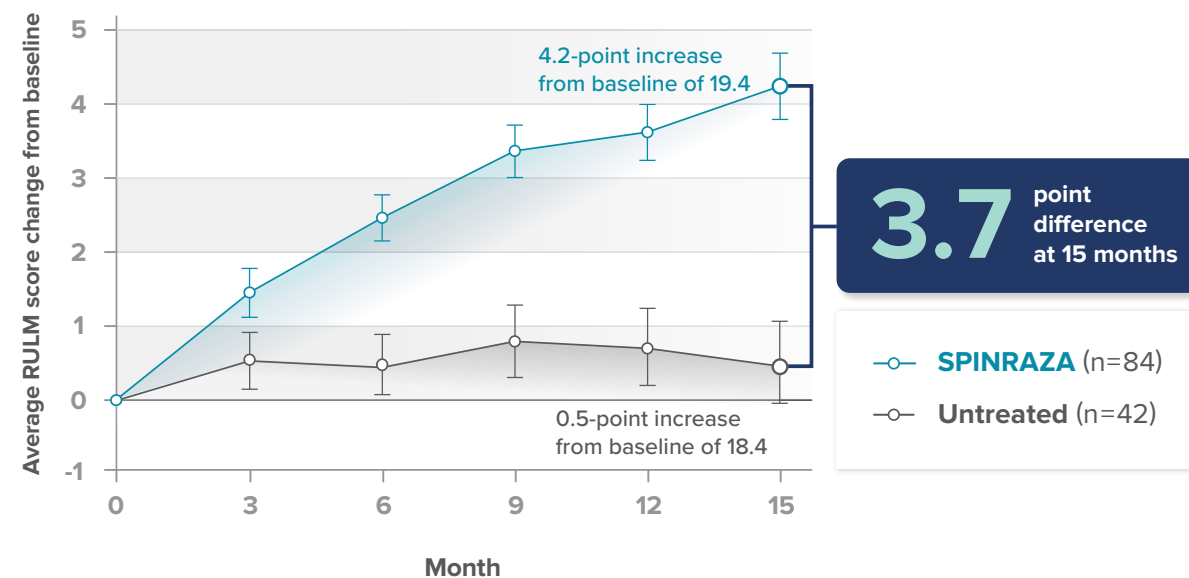


Clinically meaningful change in HFMSE scores



A 1- or 2-point improvement in HFMSE is considered a positive change, and a ≥ 3 -point improvement is considered a clinically meaningful change

Average RULM scores improved at 15 months



Revised upper limb module (RULM) scores range from 0 to 37, with higher scores indicating better function.



LILY
ON SPINRAZA

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ŁUSAKOWSKA STUDY

A real-world study for older children and adults on SPINRAZA with an extensive follow-up period of up to 30 months

The Łusakowska study was independent and not conducted or controlled by Biogen.

This study looked at how well patients were doing in different activities, using different assessments dependent on their functional abilities (HFMSSE [n=73 ambulatory and sitters], RULM [n=51, used for nonambulatory and ambulatory patients], CHOP INTEND [n=47, used for non or weak sitters], 6MWT [n=27], and PGI-I).

Highlights of the study:

- Included 120 children and adults (5 to 66 years old) with SMA (Types 1c-3)
- One of the longest real-world studies, with individuals assessed for up to 30 months
- Most individuals (73%) had SMA Type 3, and the average age at baseline was 32 years
- Safety reported in the study is generally consistent with the safety reported in the SPINRAZA clinical trials

Limitations of the study

Observational study that does not include a comparison with an untreated group. This type of study is valuable, but not as strong as a pivotal study.

The study was conducted at multiple treatment centers in Poland; practices may vary by country.

Only 12 participants had SMA Type 1c and 19 had SMA Type 2.

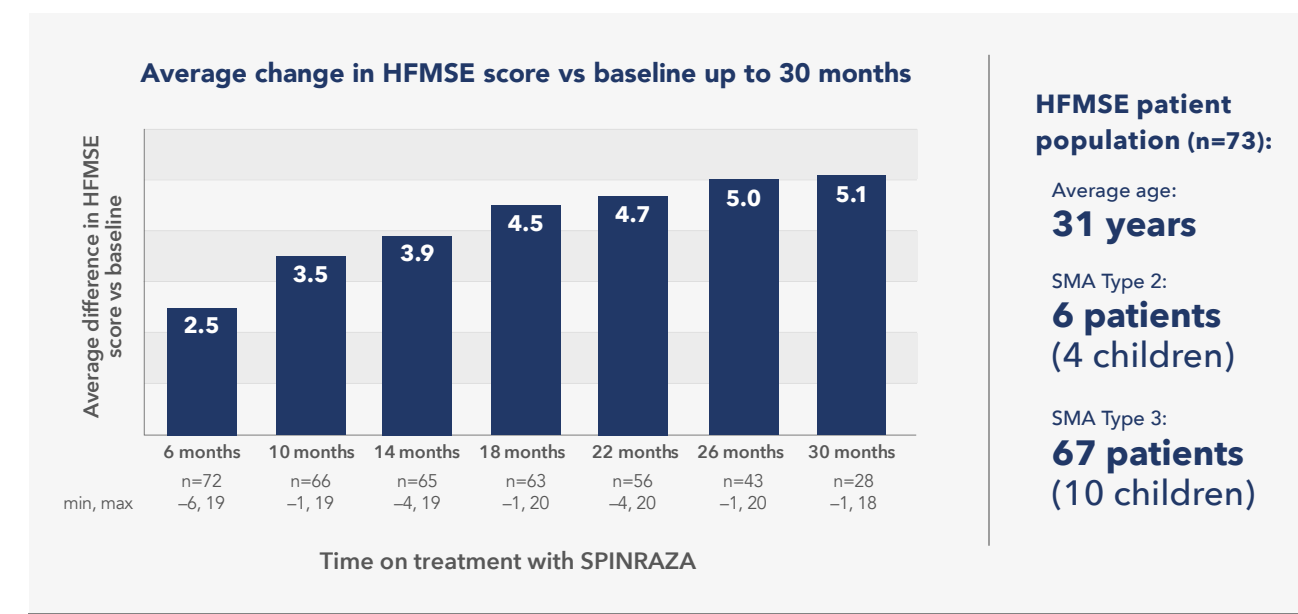
The dosing schedule in the study was different from the approved SPINRAZA schedule.

Missing data for some timepoints, some due to COVID, some because patients had not yet reached those timepoints.

The scale used to measure self-reported improvement (PGI-I) relies on what patients say and hasn't been proven in SMA.



Average results showed improvement in motor function at each timepoint compared with baseline



- Over the course of treatment, **average HFMSSE scores showed improvements** compared with baseline, ranging from **2.5 points at 6 months (n=72) to 5.1 points (n=28) at 30 months**
- Proportion of patients experiencing **no change** from baseline ranged from **8% to 20%** during the study
- Proportion of patients experiencing **worsening** from baseline ranged from **1% to 8%** during the study

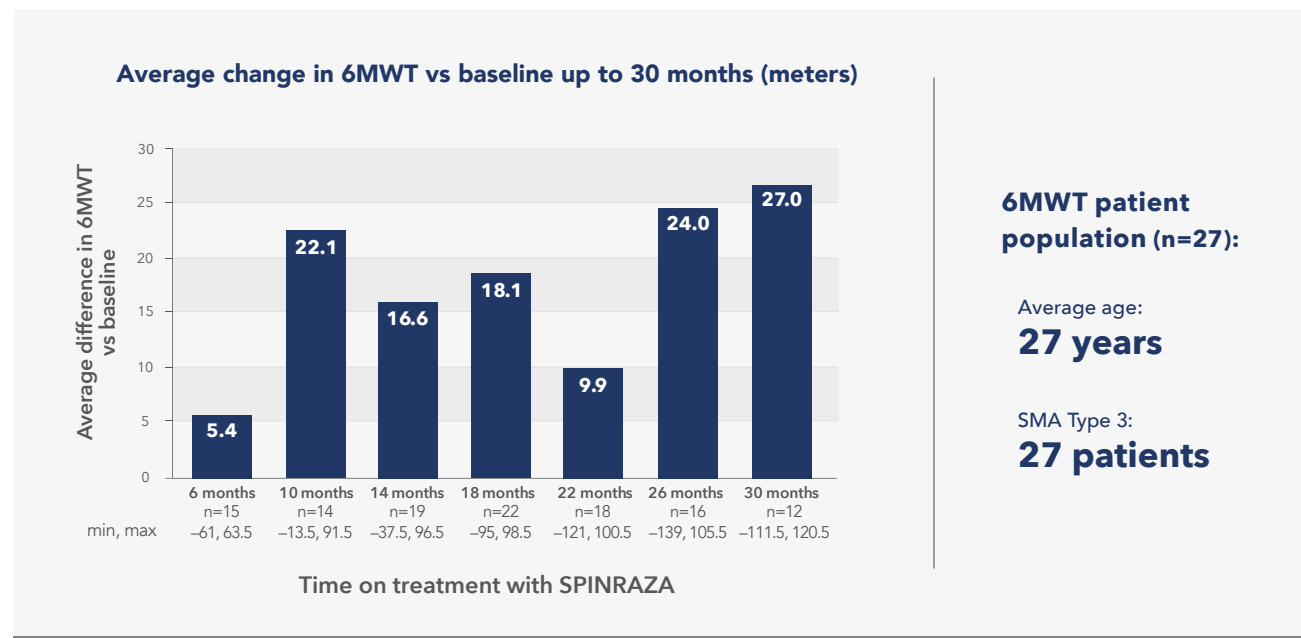
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ŁUSAKOWSKA STUDY

Average results showed improvements in walking ability based on the 6MWT at each timepoint



Results:

- Results were variable, but over the course of the study, **average 6MWT scores showed improvements** compared with baseline, ranging from 5.4 meters, or **17.7 feet (n=15), at 6 months** to 27 meters, or **88.5 feet (n=12), at 30 months**
- Proportion of **patients experiencing no change** from baseline ranged from **0% to 7% during the study**
- Proportion of **patients experiencing worsening** from baseline ranged from **14% to 50% during the study**

Patients and caregivers assessed and self-reported their status utilizing the PGI-I

At various points during the study:

- 75% to 87.5%** of patients reported an improvement
- 9% to 24%** of patients reported no change
- 0% to 5%** of patients reported feeling minimally worse
- No patients** reported feeling much worse or very much worse

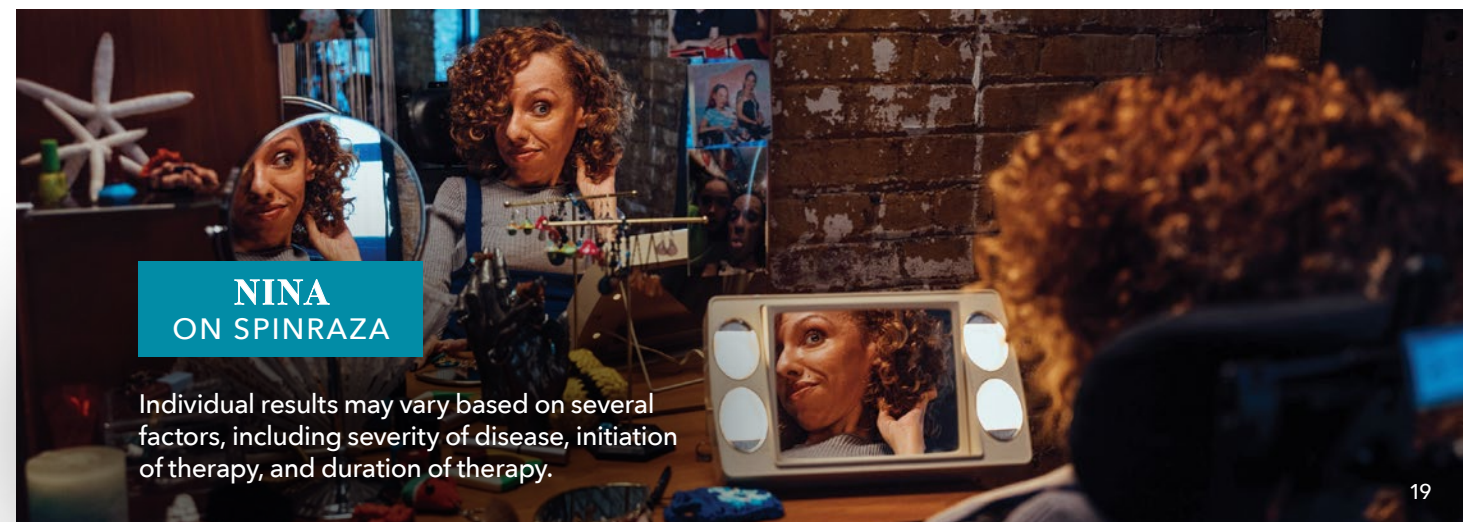
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SMARtCARE

A real-world study for teens and adults on SPINRAZA with a follow-up period of up to 38 months

This study assessed 3 functional outcome measures: HFMSE (clinically meaningful improvement defined as a change of ≥ 3 points), RULM (clinically meaningful improvement defined as a change of ≥ 2 points), and 6MWT (for ambulatory individuals, clinically meaningful improvement defined as an increase in walking distance by ≥ 30 meters)

Highlights of the study:

- Included 237 teens and adults between the ages of 16 and 71 years old, with an average age of 36 years*
- One of the longest real-world evidence studies, with individuals assessed for up to 38 months
- Included individuals with SMA Types 1, 2, 3, and 4

*Functional outcomes were assessed at baseline, 14, 26, and 38 months of treatment

Limitations of the study

Observational study does not include a comparison with an untreated group. This type of study is valuable, but not as strong as a pivotal study.

Limited to patients from 3 countries—Austria, Germany, Switzerland; practices may vary by country.

Limitations of HFMSE and RULM in capturing the full range of possible responses.

The dosing schedule in the study was different from the approved SPINRAZA schedule.

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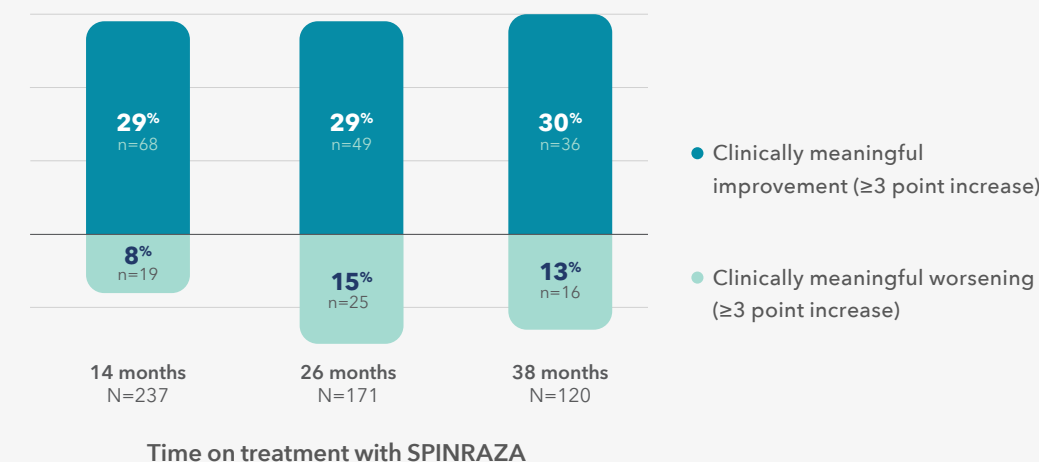
Average results showed improvement in motor function at each timepoint compared with baseline*

Primary endpoint: Change in HFMSE from baseline



*At baseline, 2 patients had a full score (66 points) and 55 patients scored 0 points.

Proportion of patients with clinically meaningful change in HFMSE score vs baseline up to 38 months



- **41% of patients (28/68)** with clinically **meaningful improvement** in HFMSE score at 14 months maintained this improvement for ≥ 38 months[†]
- Clinically **meaningful worsening** in HFMSE score was seen in **8%, 15%, and 13% of patients** at 14, 26, and 38 months, respectively

[†]Functional outcomes were assessed at baseline, 14, 26, and 38 months of treatment.

SMARtCARE

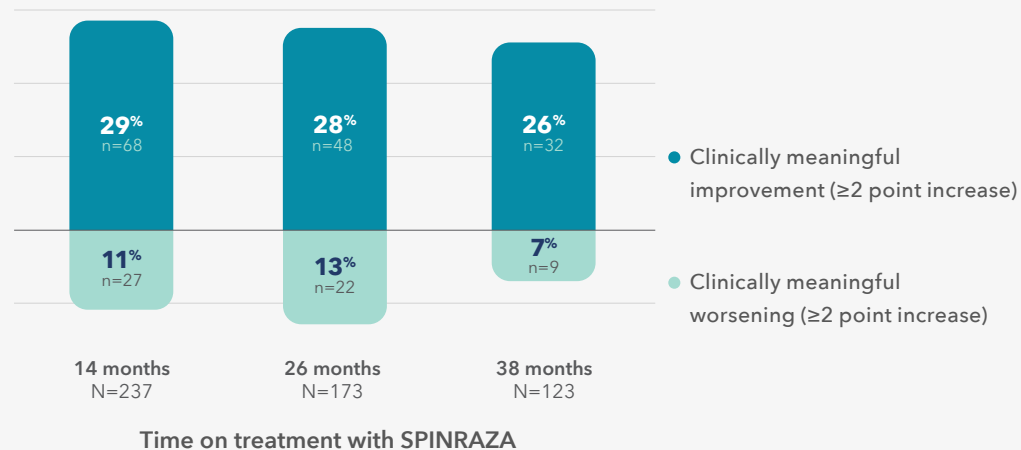
Average results showed improvement in upper limb function at each timepoint compared with baseline*

Average improvement in RULM from baseline

Average Improvement	0.75 14 MONTHS (N=237)	0.65 26 MONTHS (N=173)	0.72 38 MONTHS (N=123)
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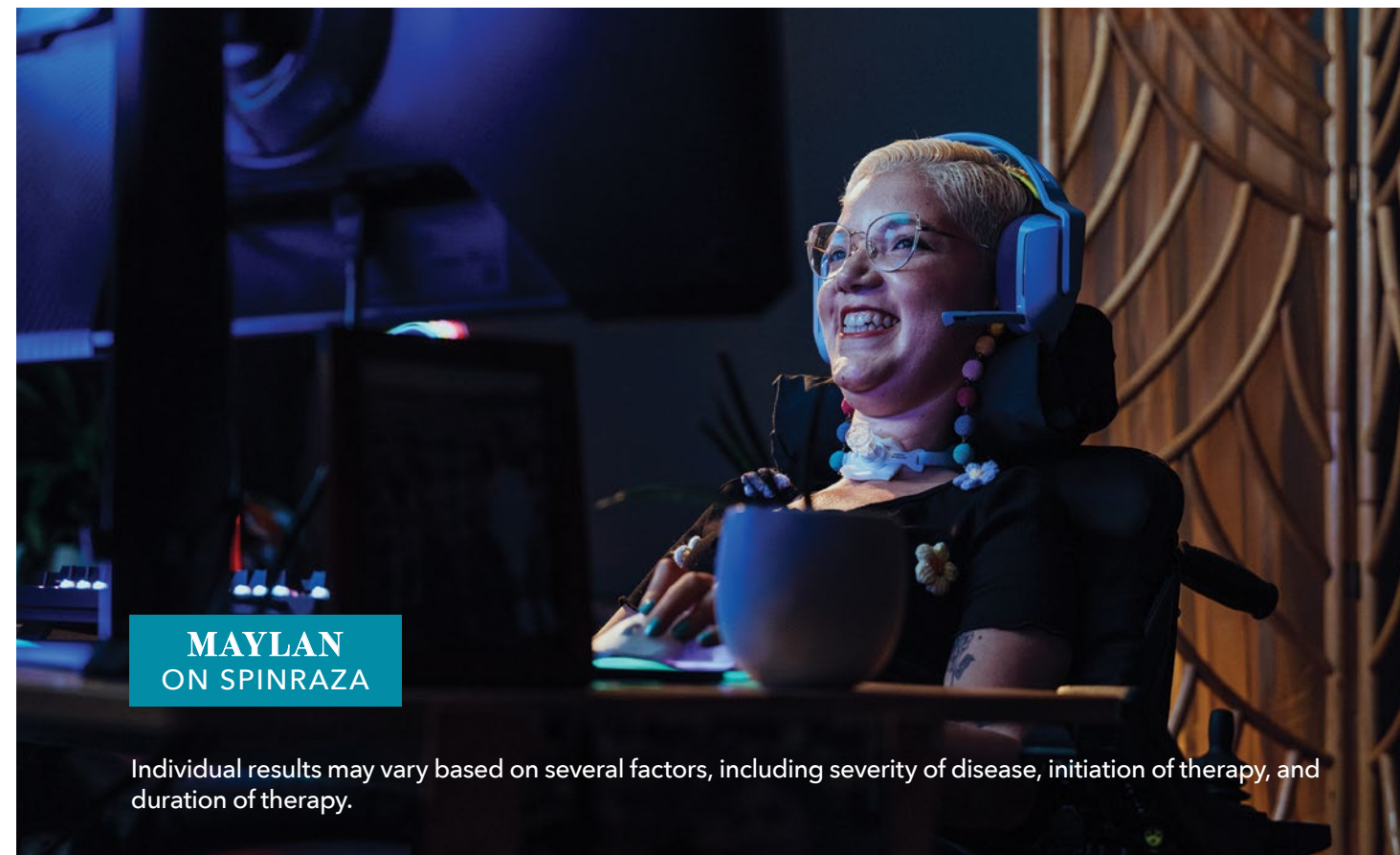
*At baseline, 74 patients had a full score (37 points) and 17 patients scored 0 points.

Proportion of patients with clinically meaningful change in RULM score vs baseline up to 38 months



- **37% of patients (25/68)** with clinically **meaningful improvement** in RULM score at 14 months maintained this improvement at 38 months[†]
- Clinically **meaningful worsening** in RULM score was seen in **11%, 13%, and 7% of patients** at 14, 26, and 38 months, respectively

[†]Functional outcomes were assessed at 14, 26, and 38 months of treatment.



Individual results may vary based on several factors, including severity of disease, initiation of therapy, and duration of therapy.

Regardless of ambulatory status, **improvement in average HFMSE and RULM scores** were reported with SPINRAZA.

SELECTED IMPORTANT SAFETY INFORMATION

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NURTURE SUPPORTIVE STUDY

Early SPINRAZA treatment has helped presymptomatic infants with SMA progress with sitting and walking motor milestones

- **Who:** 25 infants 6 weeks of age and younger who had not yet shown symptoms of SMA
- **Study time:** A supportive study with results up to 5 years
- **Primary outcome:** Time to death or respiratory intervention
- **Secondary outcome:** The effect SPINRAZA has on reaching WHO motor milestones
- **Limitations:** Small number of participants. The study is open-label, which means all infants received SPINRAZA and there is not an untreated group for comparisons
- **Safety:** Consistent with the SPINRAZA Prescribing Information

See more pediatric stories
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**MAVRIK
ON SPINRAZA**

Individual results may vary based on several factors, including severity of disease, initiation of therapy, and duration of therapy.

After 14 months:

- In an interim analysis performed after all infants had received SPINRAZA for at least 14 months (median, 25 months; range, 14 to 34 months)
 - 100% (25/25) of infants were alive without the need for permanent respiratory intervention
 - 100% (25/25) were sitting without support
 - 88% (22/25) were walking with assistance
 - 77% (17/22) were walking independently

After nearly 5 years of follow-up*:

- 100% (25/25) of presymptomatic infants were alive without permanent ventilation after a median follow-up of 4.9 years in the study
- 84% (21/25) never required respiratory intervention†

After nearly 5 years, the majority of infants achieved the following WHO motor milestones at age-appropriate times:

100%
25 OUT OF 25
were sitting
without support

96%
24 OUT OF 25
were walking
with assistance

92%
23 OUT OF 25
were walking
independently

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*Median, 4.9 years; range, 3.8 to 5.5 years.

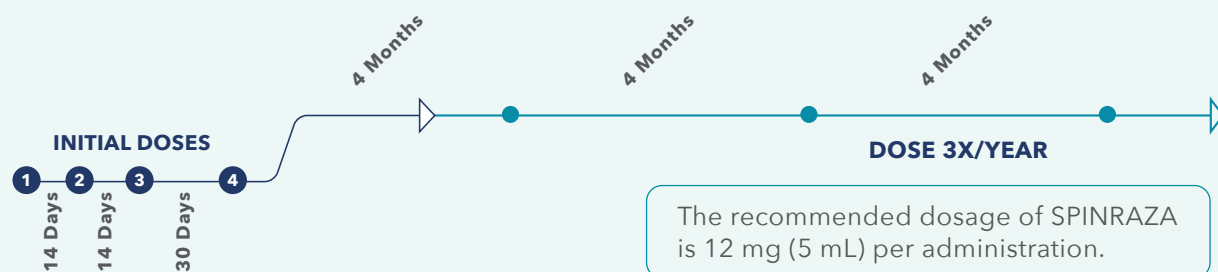
†Respiratory intervention was defined as ventilation for ≥6 hours/day continuously for ≥7 days, or tracheostomy. Permanent intervention is defined as equal or greater than 16 hours/day continuously for greater than 21 days in absence of an acute reversible event or tracheostomy.

DOSING/SAFETY



SPINRAZA is given by a doctor only 3X a year to treat SMA, after initial starting doses

SPINRAZA dosing schedule



The dosing schedule begins with 4 initial loading doses; the first 3 occur in 14-day intervals and the fourth dose 30 days after the third dose. After these initial doses, SPINRAZA is administered in maintenance doses 3 times a year. Ask your healthcare provider for additional information about the dosing schedule and treatment procedure.



Blood and urine testing

Because an increased risk of bleeding and kidney damage has been seen with similar medications, individuals taking SPINRAZA may be at similar risk. It is recommended your HCP perform blood and urine testing once before starting treatment and again before each dose to monitor for signs of these risks.

Have you missed a dose?

TALK TO YOUR DOCTOR ABOUT SCHEDULING YOUR MISSED DOSE AS SOON AS POSSIBLE.

For help with logistical support, speak with a Lead Case Manager at 1-844-4SPINRAZA (1-844-477-4672) Monday through Friday from 8:30 AM to 8:00 PM ET

WHAT IS SPINRAZA?

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Please see full [Prescribing Information](#).

This information is not intended to replace discussions with your healthcare provider.

There are SPINRAZA treatment centers all across the US

FIND ONE AT [SPINRAZA.com/locator](https://www.spinraza.com/locator)



DOSING/SAFETY

Ways to help with on-time dosing

Just starting or restarting SPINRAZA? Here's how to plan for your first treatment:

Your Family Access Manager (FAM) will be in touch with both you and the treatment center to ensure everything is in place for your first treatment. You can also help prepare by:

- Making sure your pretreatment lab work is completed
- Calling the treatment center to confirm your appointment and the check-in process
- Securing transportation to the treatment center
- Allowing extra time for parking on the day of dosing

Already on SPINRAZA?

As you continue your treatment journey with SPINRAZA, it is important to follow the dosing schedule. By working closely with your doctor and adhering to your treatment plan, you can determine how you are responding to SPINRAZA and track toward your treatment goals.

Ways to help ensure you stay on time with your treatment:

- Understand your health plan's coverage and approval criteria (genetic testing, motor function testing, laboratory results, clinical notes)
- Communicate with your care team and FAM to ensure timely submission of authorizations
- Prioritize and track clinic, physical therapy, and dosing appointments
- Don't hesitate to talk to your FAM about any questions or concerns you have about accessing your SPINRAZA treatment. Your FAM is always here to help

Get support and resources throughout your SPINRAZA journey
LEARN MORE AT SPINRAZA.com



Please see [Important Safety Information](#) on page 27 and full [Prescribing Information](#).

SUPPORT

Meet your Biogen Family Access Manager (FAM)

Wherever you are on your SPINRAZA journey, Biogen is here every step of the way with a suite of support services to help with logistics surrounding your treatment.* Your **FAM** will be your go-to person and can address any questions or concerns you may have, and help you navigate or stay on track with your treatment. This includes:



Treatment coordination



Insurance benefits investigation

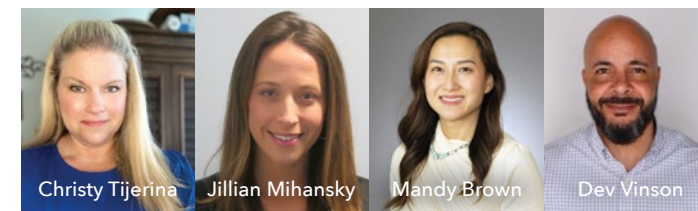


Financial assistance for eligible individuals

Please remember that your doctor should be your primary resource for any questions related to SMA and SPINRAZA.

Interested in starting SPINRAZA? Talk to your doctor today, or call 1-844-477-4672

*These services from Biogen are available only to those who have been prescribed SPINRAZA and are US residents.



See all of our support services at
SPINRAZA.com/support



Speak with a Lead Case Manager
1-844-4SPINRAZA
 (1-844-477-4672)

Monday through Friday
 from 8:30 AM to 8:00 PM ET

FOR ADULTS, CHILDREN, AND INFANTS WITH SPINAL MUSCULAR ATROPHY (SMA)

 **SPINRAZA**[®]
(nusinersen) injection
12 mg/5 mL

14,000 PEOPLE HAVE
BEEN TREATED WITH
SPINRAZA.*

DISCOVER HOW IT MAY
HELP YOU

CONSIDERING RESTARTING OR STARTING SPINRAZA?
TALK TO YOUR DOCTOR TODAY



Individual results may vary based on several factors, including severity of disease, initiation of treatment, and duration of therapy.

SELECTED IMPORTANT SAFETY INFORMATION

The most common side effects of SPINRAZA include lower respiratory infection, fever, constipation, headache, vomiting, back pain, and post-lumbar puncture syndrome.

These are not all of the possible side effects of SPINRAZA. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at **1-800-FDA-1088**.

Before taking SPINRAZA, tell your healthcare provider if you are pregnant or plan to become pregnant.

Please see additional Important Safety Information on page 27 and full Prescribing Information.

*Based on commercial patients and early access patients receiving treatment with SPINRAZA worldwide as of June 2024.