Approved by Sterling IRB, IRB ID: 14739

KLK2

PASenger STUDY

A clinical trial evaluating an investigational medication for people with metastatic hormone-resistant prostate cancer

If you are caring for someone who has progressive metastatic hormone-resistant prostate cancer, a clinical trial evaluating an investigational medication may be an option. This booklet will help you learn more about the study.

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What is the KLK2-PASenger Study?

The KLK2-PASenger Study is testing an investigational medication in combination with chemotherapy for people with metastatic hormone-resistant prostate cancer who are progressing on their current therapy. Progressive metastatic means that the cancer is advancing and has spread to other parts of the body.

Chemotherapy is a standard-of-care treatment for people with this type of prostate cancer. The investigational medication is being studied to see how safe and effective it may be when used along with chemotherapy.

What is the investigational medication?

The investigational medication is an antibody-like drug that attaches to the T cells (part of a type of white blood cells in the immune system) and also to KLK2, a protein on the surface of the prostate cancer cells. The investigational medication attaches to both in order to bring them closer together, which may help the body's immune system target the cancer cells. Participants in the study will be randomly assigned to receive the investigational medication in combination with chemotherapy, or chemotherapy alone, which is considered standard-of-care. The safety and effectiveness of the investigational medication have not been established.

Participants will have a 1 in 2 (50%) chance of getting the investigational medication with chemotherapy, and a 1 in 2 (50%) chance of getting chemotherapy alone. The investigational medication and chemotherapy are each given by intravenous (IV) infusion. An IV infusion is when medicine is put directly into the blood through a needle in the vein or a port-a-catheter.

As this is an open-label study, the participant and the clinical staff will know if the participant is receiving the investigational medication with chemotherapy or chemotherapy alone.

Who is eligible to join the KLK2-PASenger Study?

To join the trial, participants must:

- Be 18 years old or older.
- Have been diagnosed with hormone-resistant prostate cancer that has spread to other parts of the body (metastasized).
- Have been treated with at least 1 oral hormone therapy but no more than 2 different oral hormone therapies (abiraterone acetate, enzalutamide, apalutamide, and darolutamide).

There are other requirements to participate. The clinical staff can provide more information.

Additional information about participating

- All participants will receive chemotherapy, which is a standard-of-care treatment option.
- All study-related tests and procedures, as well as the investigational medication and chemotherapy, will be provided at no cost.
- Participants will be regularly seen and closely monitored by the study doctor and clinical staff who specialize in metastatic prostate cancer.
- Participating in this research study will contribute to a greater understanding of metastatic hormone-resistant prostate cancer and the investigational medication.

Before joining, the clinical staff will review:

- What will happen during the study.
- Side effects that may occur.

Safety is our highest priority during the clinical trial. If there are any questions or concerns at any point, talk to the study doctor or a member of the clinical staff.

Participation in any clinical trial is voluntary. Participants are free to stop taking part at any time for any reason, but ideally should discuss with their study team prior to doing so. Privacy will be maintained throughout the study.

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What happens if my loved one joins the clinical trial?

There are 3 periods to the trial: Screening, Treatment, and Follow-up.

- **Screening Period:** This takes up to 4 weeks. Participants will go to a trial site for tests and procedures to see if they qualify.
- **Treatment Period:** All participants will receive chemotherapy. Half of participants (50%) will also receive the investigational medication. In addition, participants will have tests and procedures to evaluate their disease and overall health. These include, but are not limited to, physical exams, imaging (CT/MRI/bone scan), blood tests, and questionnaires. Participants will also complete an end-of-treatment visit.
- **Follow-up Period:** Participants will continue in-person visits and assessments during post-treatment follow-up every 6 weeks to evaluate how well the investigational medication and chemotherapy work over a longer period of time. When there is a change in the participant's disease or health status requiring a change to the treatment plan, participants will continue survival follow-up every 12 weeks until study withdrawal. These survival follow-up visits can be done by phone or through chart review.

How can I support the trial participant?

Below are some suggested ways to support the trial participant:

- Help them plan upcoming clinical visits.
  - » Assist with scheduling, if needed.
  - » Arrange transportation, if needed (the clinical staff can provide details on reimbursement that may be provided for ride shares and other travel-related expenses).
- Attend trial visits with them if they would like.
- Encourage them to bring books and magazines for the longer visits.
- Familiarize yourself with the schedule and potential side effects of the investigational medication, chemotherapy, and other medications that may be prescribed by the study doctor.
- Check in with the participant between visits to see how they are feeling.
  - » Watch out for side effects.
  - » Provide emotional support as needed.
- Notify the clinical staff right away if you or the participant has questions or concerns.
  - » Get emergency help if needed.

Treatment Groups

Investigational Group			
Trial Therapy	**Duration**	**Visits**	
Investigational medication	Until a change in your disease or health status	3 visits for Cycle 1 (8 weeks) 1 visit for Cycle 2 until the end of treatment (6 weeks per cycle)	The intravenous (IV) infusion will take 30-60 minutes. On days with chemotherapy, infusion will start at least 1 hour after chemotherapy
Chemotherapy	Approximately 30 weeks	2 visits for Cycle 1 (8 weeks) 2 visits for Cycle 2 to 5 (6 weeks) (up to 10 doses)	The intravenous (IV) infusion will take 60 minutes

Comparator Group			
Trial Therapy	**Duration**	**Visits**	
Chemotherapy	Approximately 30 weeks	1 visit every 3 weeks (up to 10 doses)	The intravenous (IV) infusion will take 60 minutes

All participants will receive premedication prior to receiving the investigational medication or chemotherapy.

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Understanding metastatic prostate cancer research

KLK2-PASenger is a Phase 3 clinical trial. Phase 3 clinical trials are used to demonstrate how safe and effective a therapy may be in a larger group of people. It is the last stage of research before the therapy being evaluated may be approved for use.

It is only through clinical trials like this that doctors and researchers are able to collect information to help them learn more about metastatic prostate cancer and how they may be able to treat it.

Want to learn more about the trial?

For more information and to see if the person you provide care for may qualify to participate, please contact:

Trial site:

Contact person:

Address:

Phone:

Email:

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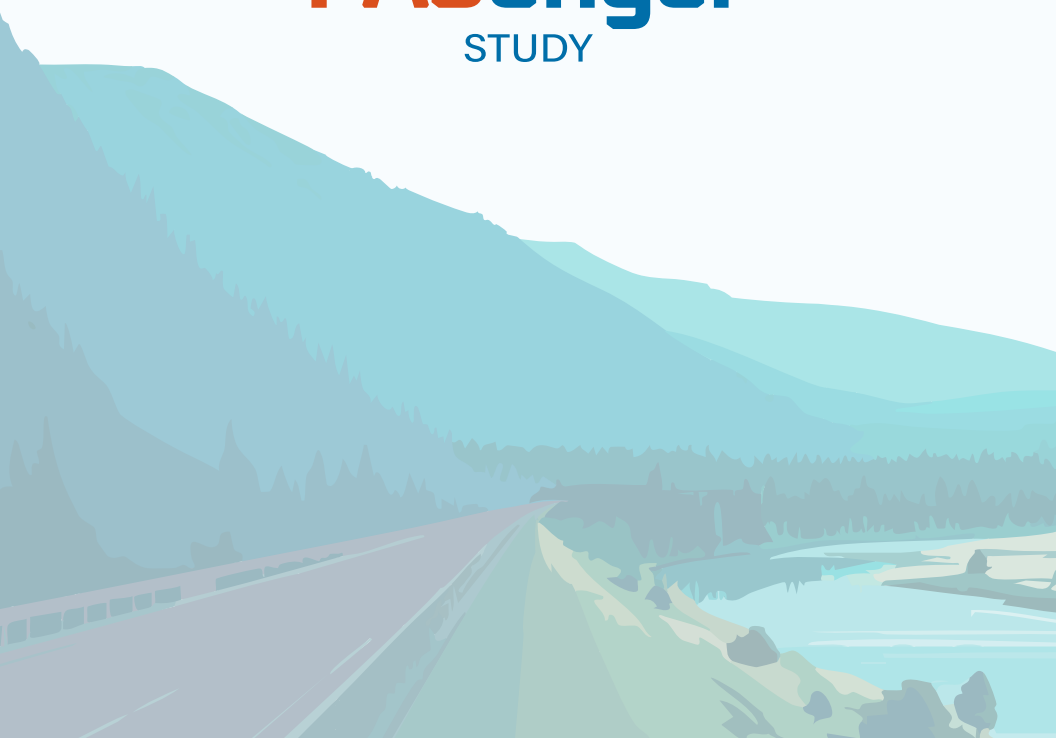
KLK2 PASenger STUDY



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Now Enrolling:

Prostate Cancer Study

Seeking people with metastatic hormone-resistant prostate cancer.

KLK2 PASenger STUDY

About the KLK2-PASenger Study

The KLK2-PASenger Study is testing if an investigational medicine, in combination with chemotherapy, is safe and effective for people with metastatic prostate cancer that has spread to other parts of the body (metastasized) on current therapy.

If you qualify and choose to participate, you will be randomly assigned to receive the investigational medication in combination with chemotherapy, or chemotherapy alone, which is considered standard of care. You will have a 1 in 2 (50%) chance of getting the investigational medication with chemotherapy, and a 1 in 2 (50%) chance of getting chemotherapy alone. As this is an open-label study, you and the clinical staff will know if you are receiving the investigational medication with chemotherapy or chemotherapy alone. The safety and effectiveness of the investigational medicine have not been established.

The investigational medication and chemotherapy are given by intravenous (IV) infusion. An IV infusion is when a medicine is put directly into your blood through a needle in your vein or a port-a-catheter.

How Do I Qualify?

If you want to be part of this study, you need to:

- Be 18 years old or older
- Have been diagnosed with hormone-resistant prostate cancer that has spread to other parts of your body (metastasized)
- Have been treated with at least 1 oral hormone therapy but no more than 2 different oral hormone therapies (abiraterone, enzalutamide, apalutamide, and darolutamide)

There are other requirements to participate. The clinical staff will give you more information.

What Should I Know About This Study?

Participating in this research study could help better understand this combination treatment and determine if it is safe and effective for metastatic hormone-resistant prostate cancer.

Participants will receive all study-related tests and procedures, as well as the investigational medication and chemotherapy, at no cost. The clinical staff can give you more information about additional reimbursement for other costs.

For more information, please contact:

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For more information, please contact:

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CRC COVER LETTER

For vTMF submission use only. Please complete all boxes and use 'N/A' if not applicable.

Study Name	PAS-3003 (PASenger)
Compound Name/Identifier	JNJ-78278343
Protocol ID	78278343PCR3001; Phase 3
Item Name	PAS-3003 (PASenger) Patient Recruitment Website
Item Purpose	The PASenger patient recruitment website contains information about the clinical trial, information about mHRPC, information on who can take part, FAQs, and resources. The goal is to inform potential patients about our clinical research study and on how to participate. The page will be hosted on the J&J Clinical Trials platform. The templated format of this PRW has been approved with VTMF- 23606810. Copy has largely been pulled from PASenger Patient Guide document (VTMF-24009641) and Caregiver Guide (VTMF-24003239) Copy for PRWs related to OUS referrals has been implemented (**VTMF-23667649**)
Intended Audience/Recipient for This Material (Check all that apply)	☒ Potential Patients / General Public or Community ☒ Enrolled Patients ☐ J&J Study HCPs ☐ Site Staff ☒ External HCPs ☒ Study Team or CRO ☐ CRC Reviewers Only (New Concept)
Print/Digital/Both	☐ Print ☒ Digital ☐ Both ☐ N/A

New concept vTMF #	N/A
Any additional relevant information	N/A

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Patient Recruitment Website (PRW) for KLK2 PASenger (3003)

- This is a PRW with content specific to the PASenger 3003 study
- We are showing the screens in order as they scroll; some may need to be split.
- Linked pages within JNJ footer as well as Resources page will not be shown as they were routed for approval with the template VTMF-23606810
- Copy has largely been pulled from KLK2-comPAS Patient Guide document (VTMF-24009641) and Caregiver Guide (VTMF-24003239)
- Imagery comes from JNJ Brand center (https://brandcenter.jnj.com/)

Ab

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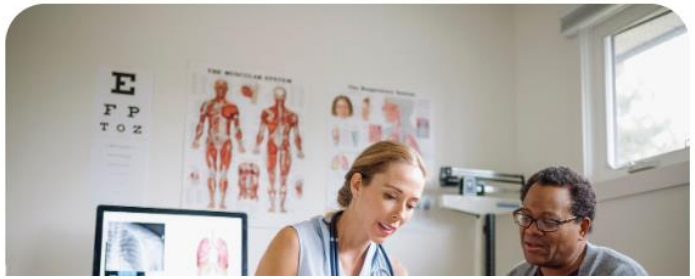
Welcome to the KLK2-PASenger Study

A study for people with hormone resistant prostate cancer that has spread to other parts of the body (metastasized).

See if you may qualify



Study Overview

The KLK2-PASenger Study is testing how safe and effective an investigational medication is for people with hormone-resistant prostate cancer that has spread to other parts of the body and is progressing. Hormone-resistant prostate cancer means the cancer is no longer responding to hormone therapy.

Everyone who participates in the study will be randomly assigned to receive the investigational

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About the study tab

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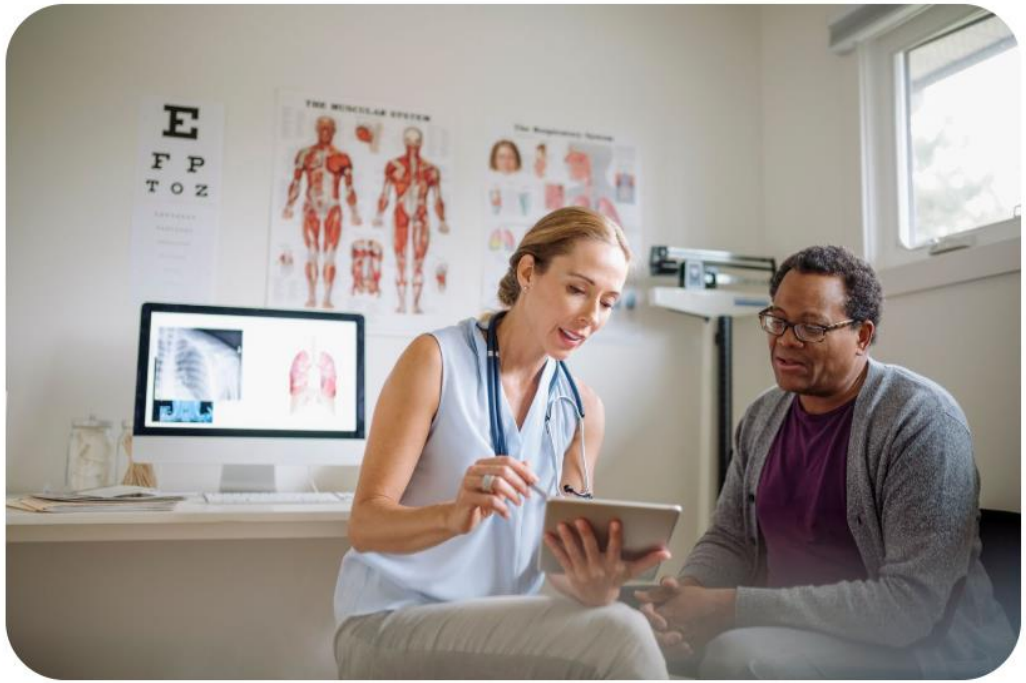

Study Overview

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Everyone who participates in the study will be randomly assigned to receive the investigational medication with chemotherapy or chemotherapy alone, which is a standard of care treatment option for advanced prostate cancer.

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Study Goals

The goal of this study is to test how well the investigational medication works with chemotherapy to stop or slow prostate cancer compared to chemotherapy alone. Though chemotherapy is an approved standard of care treatment option for metastatic prostate cancer, the combination with the investigational medication has not yet been approved.

Hormone-Resistant Metastatic Prostate Cancer

Hormone-resistant metastatic prostate cancer (mHRPC) is an advanced stage of prostate cancer that has spread beyond the prostate gland to other parts of the body (metastatic). Prostate cancer cells often need a male hormone called testosterone to grow. Hormone-resistant prostate cancer means that the cancer cells have learned to grow even when the amount of testosterone in the body is very low.

What Happens During This Study?

About the study tab

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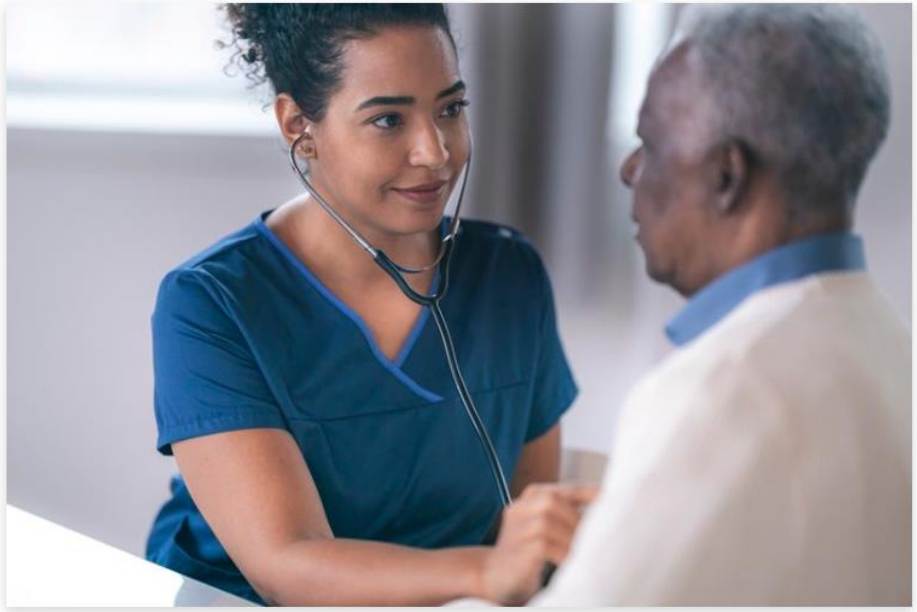
What Happens During This Study?

Participants will be randomly assigned (like the flip of a coin) to get either the investigational medication with chemotherapy or chemotherapy alone. There is a 1 in 2 (50%) chance of receiving the investigational medication with chemotherapy, and a 1 in 2 (50%) chance of receiving chemotherapy alone.



See if you

1. Are you a US resident?

About the study tab

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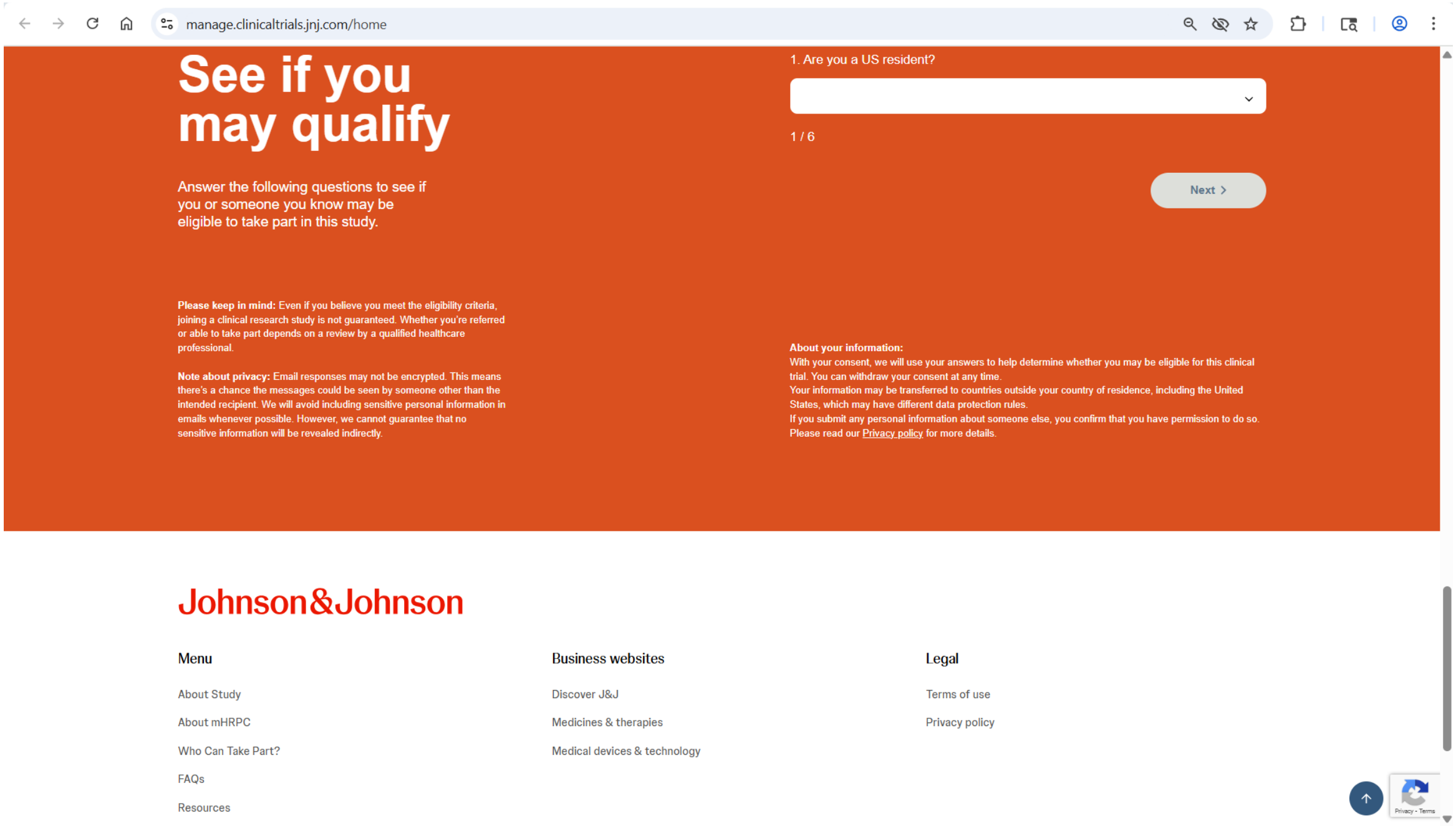

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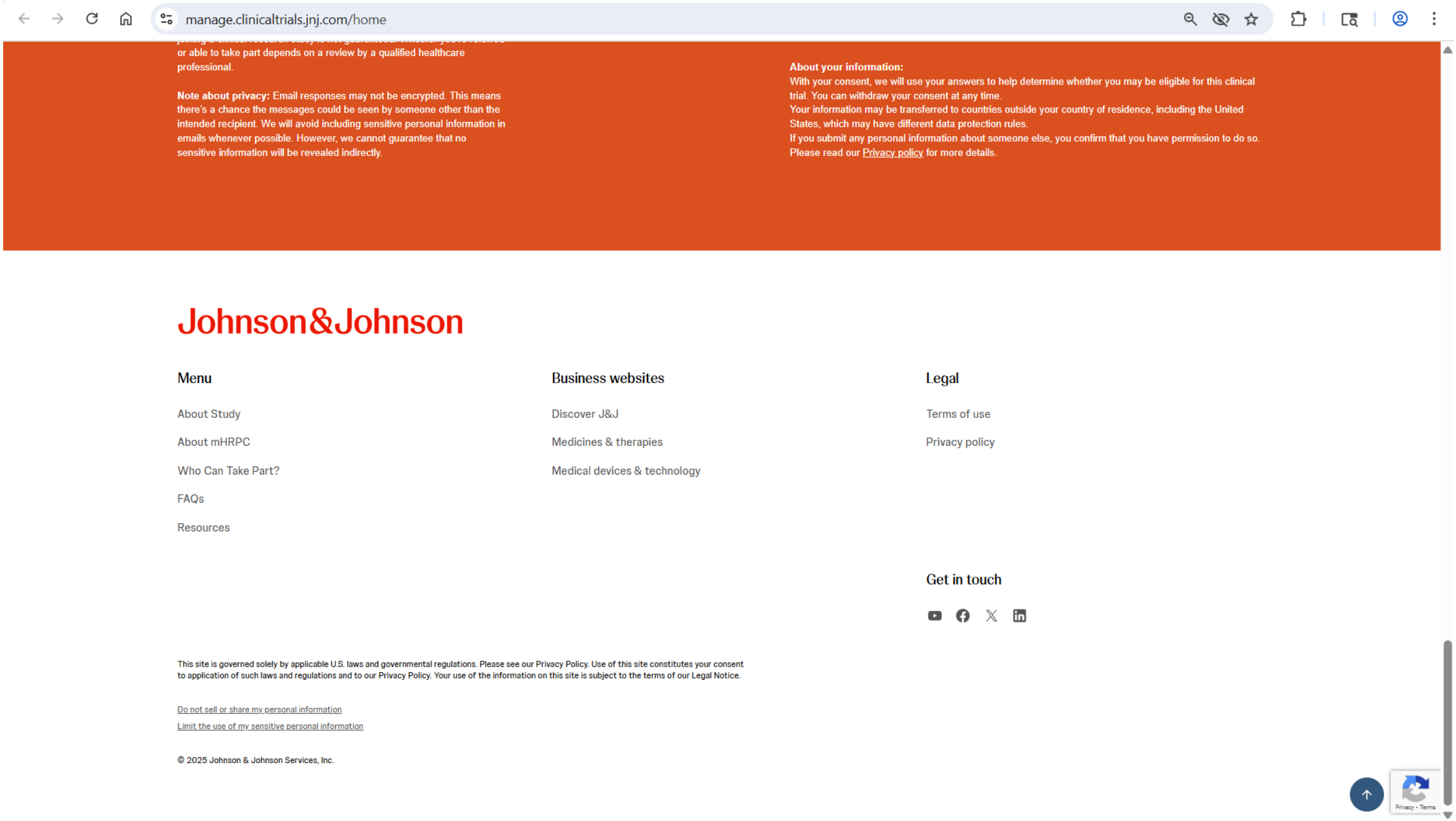

About mHRPC tab

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PASenger

About Study | About mHRPC | Who Can Take Part? | FAQs | Resources | Do I qualify?

Welcome to the KLK2-PASenger Study

A study for people with hormone resistant prostate cancer that has spread to other parts of the body (metastasized).

See if you may qualify

About Hormone-Resistant Metastatic Prostate Cancer (mHRPC)

About mHRPC tab

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About Hormone-Resistant Metastatic Prostate Cancer (mHRPC)

Hormone-resistant metastatic prostate cancer (is an advanced stage of prostate cancer that has spread beyond the prostate gland to other parts of the body (metastatic). Prostate cancer cells often need a male hormone called testosterone to grow. Hormone-resistant prostate cancer means that the cancer cells have learned to grow even when the amount of testosterone in the body is very low.

See if you may qualify

Answer the following questions to see if you or someone you know may be eligible to take part in this study.

Please keep in mind: Even if you believe you meet the eligibility criteria,

1. Are you a US resident?

1 / 6

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About mHRPC tab

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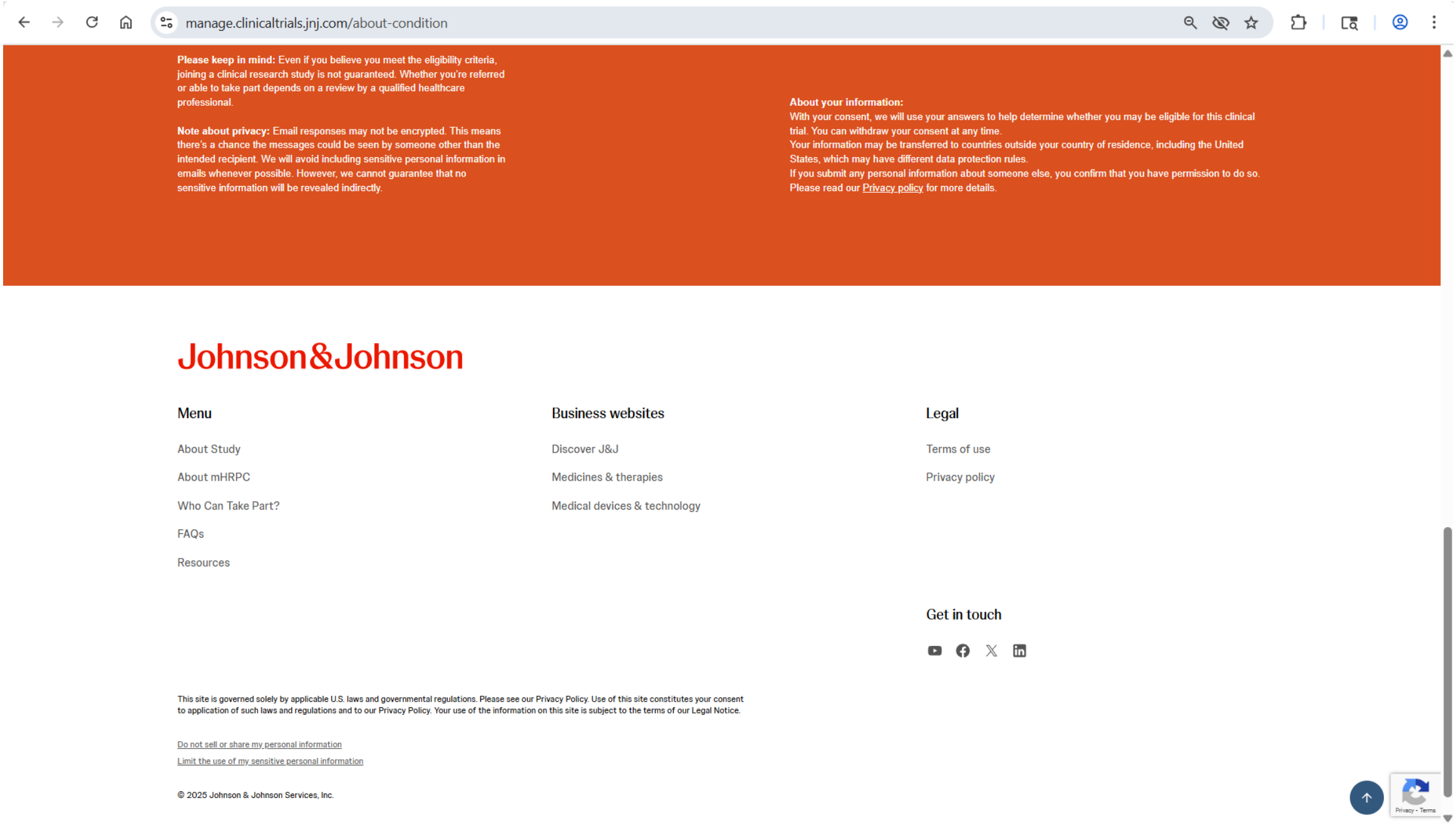

Who Can Take Part? tab

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PASenger

About Study | About mHRPC | **Who Can Take Part?** | FAQs | Resources | **Do I qualify?**

Welcome to the KLK2-PASenger Study

A study for people with hormone resistant prostate cancer that has spread to other parts of the body (metastasized).

See if you may qualify

Am I Eligible for the Study?

To qualify for the study, you will go through a screening process that may include questions about your medical history, blood tests, a CT or MRI, bone scan, and a physical exam. Check out the criteria below to see if you might be a candidate.

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Who Can Take Part? tab

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See if you may qualify

Who Can Take Part? tab

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You or your loved one can join the study if:

- You are 18 years of age or older
- You have been diagnosed with hormone-resistant prostate cancer that has spread to other parts of your body (metastasized), but not to the brain
- You have been treated with at least 1 oral hormone therapy but no more than 2 different oral hormone therapies (abiraterone, enzalutamide, apalutamide, and darolutamide)

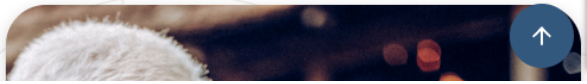
There are other requirements to participate. The clinical staff will give you more information.

You or your loved one cannot join the study if:

- You have had a solid organ or bone marrow transplant
- You have an autoimmune disease (where your immune system attacks your body) and are taking medications to suppress your immune system
- You have another cancer, other than prostate cancer, that might interfere with the study results
- You've had serious heart or stroke problems in the last 6 months

There are other requirements to participate. The clinical staff will give you more information.

What to Expect as a Participant



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What to Expect as a Participant

The study includes 3 periods: Screening, Treatment, and Follow-up

***Screening Period*:** During the Screening period, you will have tests and procedures, including imaging/scans, to see if you qualify for the study. The study doctor will answer any questions you may have and ask you to sign an Informed Consent Form (ICF) before any study-related procedures.

Treatment Period: If you qualify, you will be randomly assigned to get either the investigational medication with chemotherapy or chemotherapy alone. Both are given by IV infusion over 30 to 60 minutes. This is an open-label study, meaning that you and the clinical staff will know if you are receiving the investigational medication with chemotherapy or chemotherapy alone.

The study schedule is broken out into groups of weeks that repeat, called cycles. All cycles are 6 weeks, except for Cycle 1 (8 weeks) for patients receiving the investigational medication with chemotherapy.*

***Follow-up Period*:** The Follow-up period starts after the end-of-treatment visit and is broken into two parts – post-treatment follow-up and survival follow-up. Your study doctor will let you know when your treatment period ends, and when your end-of-treatment visit will be. Follow-up visits are every 6-12 weeks and may be done at the clinic or on the phone, depending on the phase of follow-up. Follow-up visits help us collect useful long-term information about these treatments on you and your disease.

Click the Download button to find out more information.

Download

Who Can Take Part? Tab → Download Button

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	Cycle 1 (8 weeks)				Cycles 2-5 (6 weeks)		Cycle 6 to End-of-Treatment Visit (6 weeks /cycle)
	Day 1	**Day 8**	**Day 15**	**Day 36**	**Day 1**	**Day 22**	**Day 1**
Investigational Group	Investigational medication Step-up dose 1*	Investigational Medication Step-up dose 2*	Investigational Medication + chemotherapy	Chemotherapy	Investigational Medication + chemotherapy	Chemotherapy	Investigational Medication

	Cycle 1 (6 weeks)		Cycle 2 to End-of-Treatment (6 weeks/per cycle)	
	Day 1	**Day 22**	**Day 1**	**Day 22**
Comparator Group	Chemotherapy	Chemotherapy	Chemotherapy	Chemotherapy

Who Can Take Part? tab

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Why Participation in Research Is Important

Clinical research studies may help to find better ways to treat different conditions. When people from all backgrounds participate in clinical research, it helps us understand how medicines affect people around the world who are impacted by certain conditions and diseases. Your participation may help shape the future of cancer care.

See if you may qualify

Answer the following questions to see if you or someone you know may be

1. Are you a US resident?

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Who Can Take Part? tab

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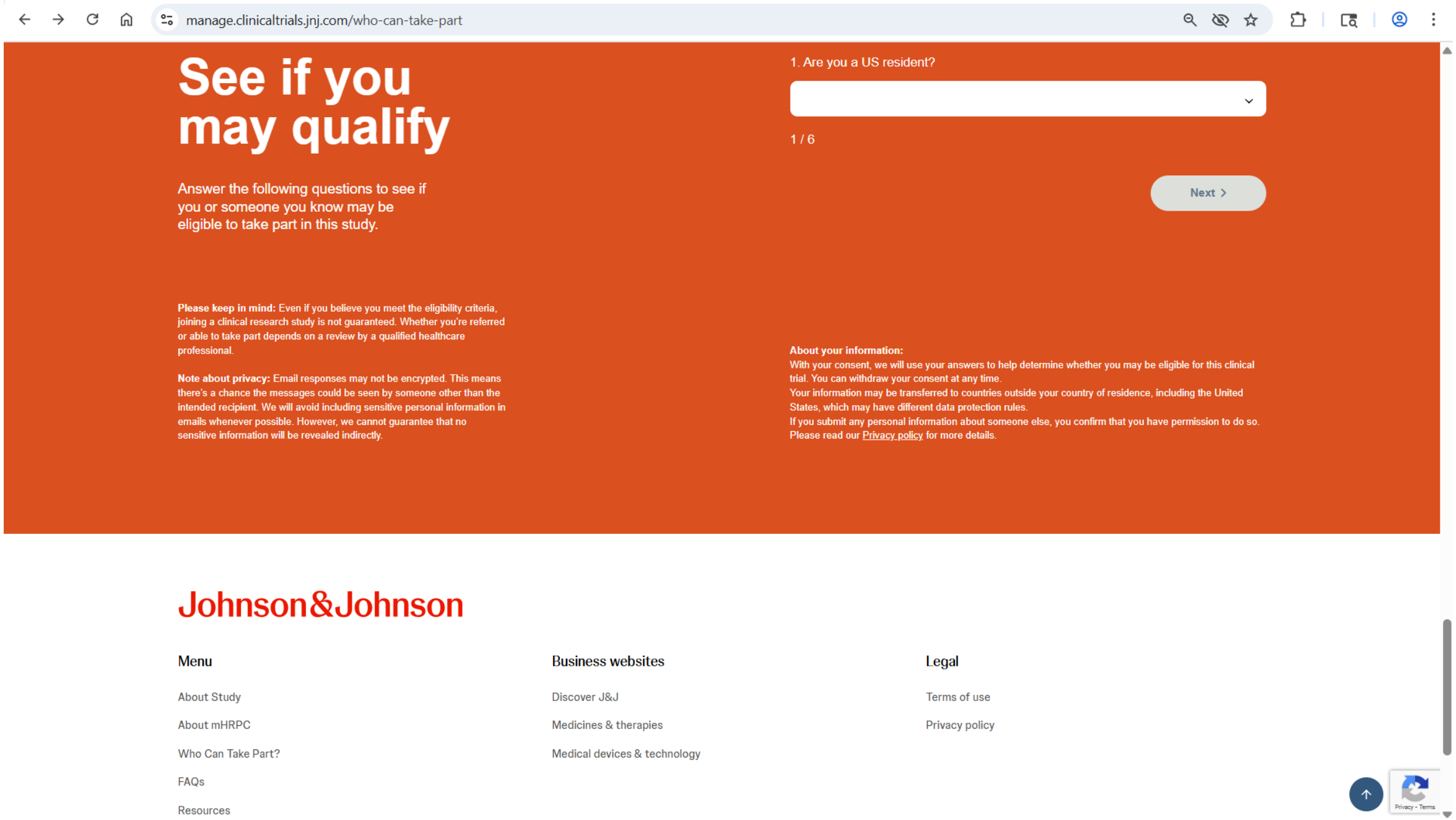

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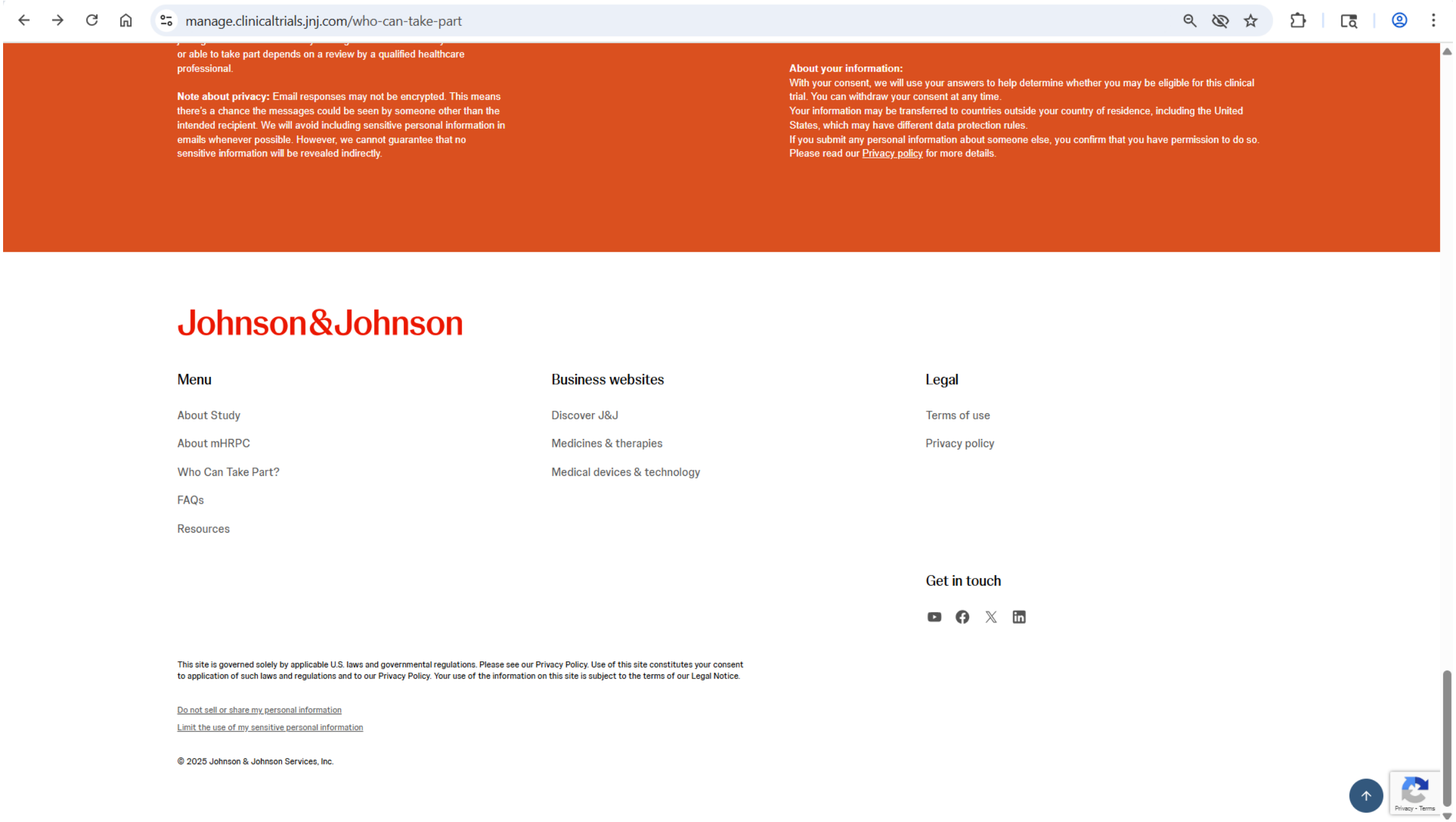

FAQs tab

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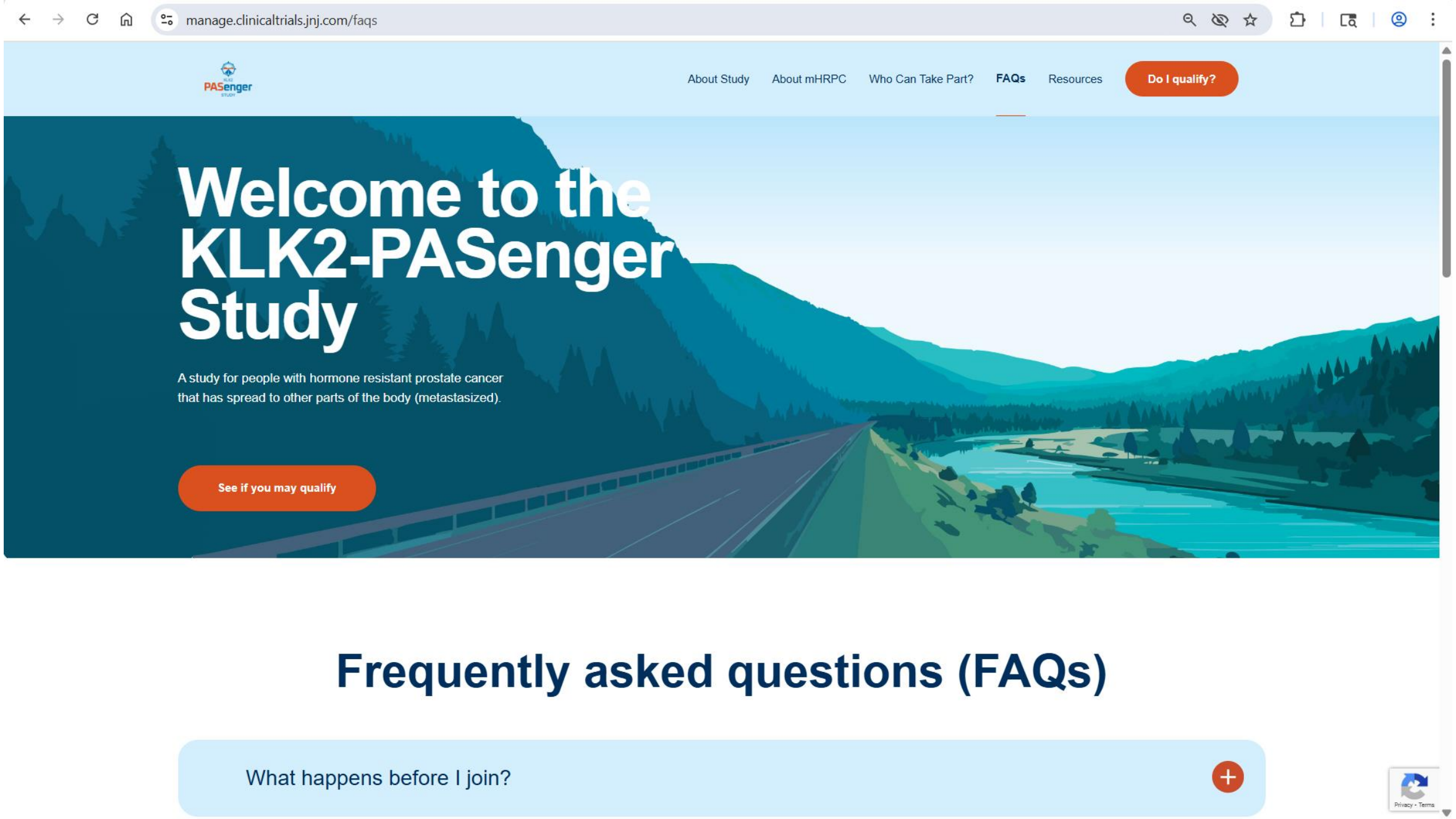

FAQs tab

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What happens before I join?

How will my privacy and personal information be protected?

What is the investigational medication?

What if I have side effects?

What if I enroll in the clinical study but then change my mind?

What is the goal of this study?

Are there risks involved?

Privacy - Terms

FAQs tab

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What happens before I join?

Before joining a clinical research study, you will go through a screening process, including tests and questions about your health. You will also review and sign a document called an Informed Consent Form (ICF) that goes over the study details, as well as the potential risks and benefits of the study. You will also be able to ask any questions you have.

How will my privacy and personal information be protected?

In a clinical research study, your identity and any medical information collected is confidential. It is only available to the people and organizations involved in the trial. Even if you give permission, you can change your mind at any time, for any reason. The samples and data that are obtained are protected and can only be used for research purposes. There are laws in place to prevent information from being shared for other purposes.

What is the investigational medication?

The investigational medication is an antibody-like medicine that attaches to the T cells (part of a type of white blood cells in the immune system) and also to KLK2, a protein on the surface of the prostate cancer cells. The investigational medication attaches to both to bring them closer together, which may help the body's immune system target the cancer cells. Participants in the study will be randomly assigned to receive the investigational medication in combination with chemotherapy, or chemotherapy alone, which is considered standard of care.

What if I have side effects?

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FAQs tab

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What if I have side effects?

You may experience side effects during the study. Before you begin participating, the clinical staff will review all the potential risks and possible side effects with you. During the study, the clinical staff will closely watch you for any study-related side effects. The study doctor will prescribe medications as needed to help with symptoms. The clinical staff can give you more information about potential side effects and how to manage them.

What if I enroll in the clinical study but then change my mind?

You may withdraw your consent to participate in receiving study treatment or withdraw consent from the whole study (including follow-up) at any time, for any reason. You may also be asked to discontinue study treatment by the clinical staff if it is deemed to be in your best interest for health reasons.

What is the goal of this study?

This study is testing whether an investigational medication is safe and effective for people with advanced prostate cancer that no longer responds to hormone therapy.

Are there risks involved?

Like all clinical trials, there are potential risks, such as side effects related to the study drug. Before you begin participating, the clinical staff will review all the potential risks and possible side effects with you. During the study, the clinical staff will closely watch you for any study-related side effects. Contact your study team if you encounter any side effects.

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FAQs tab

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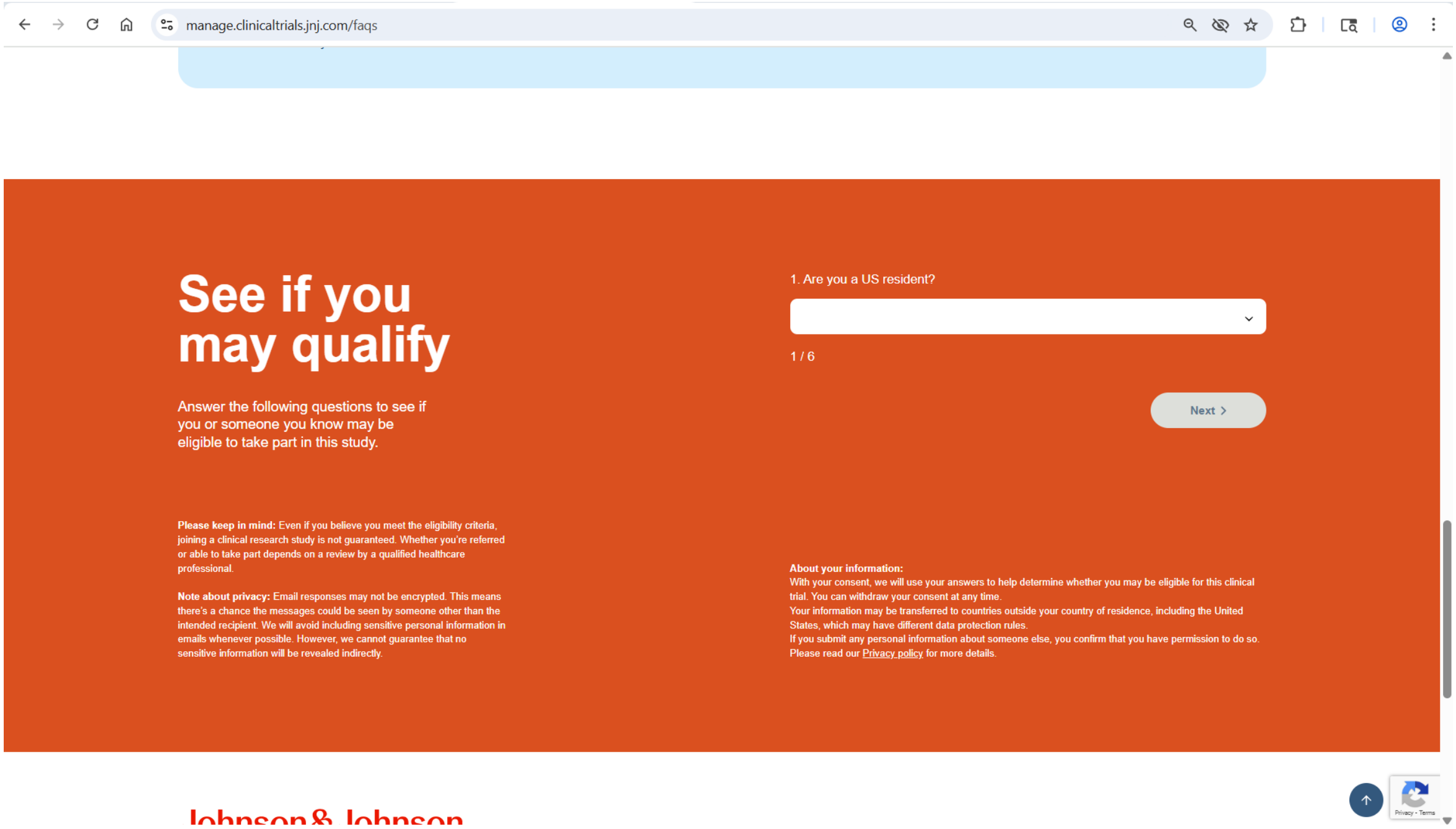

FAQs tab

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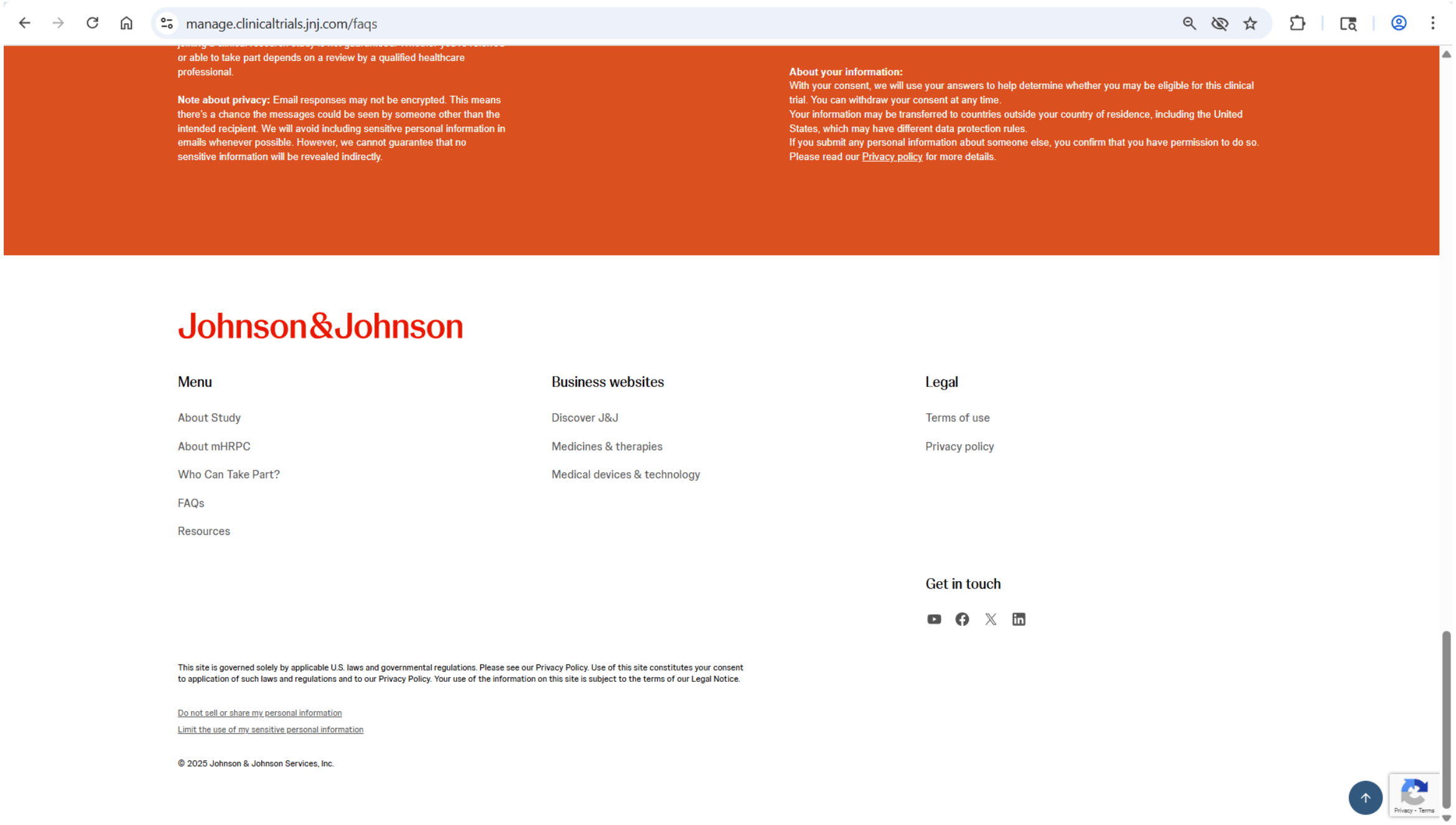

Resources tab

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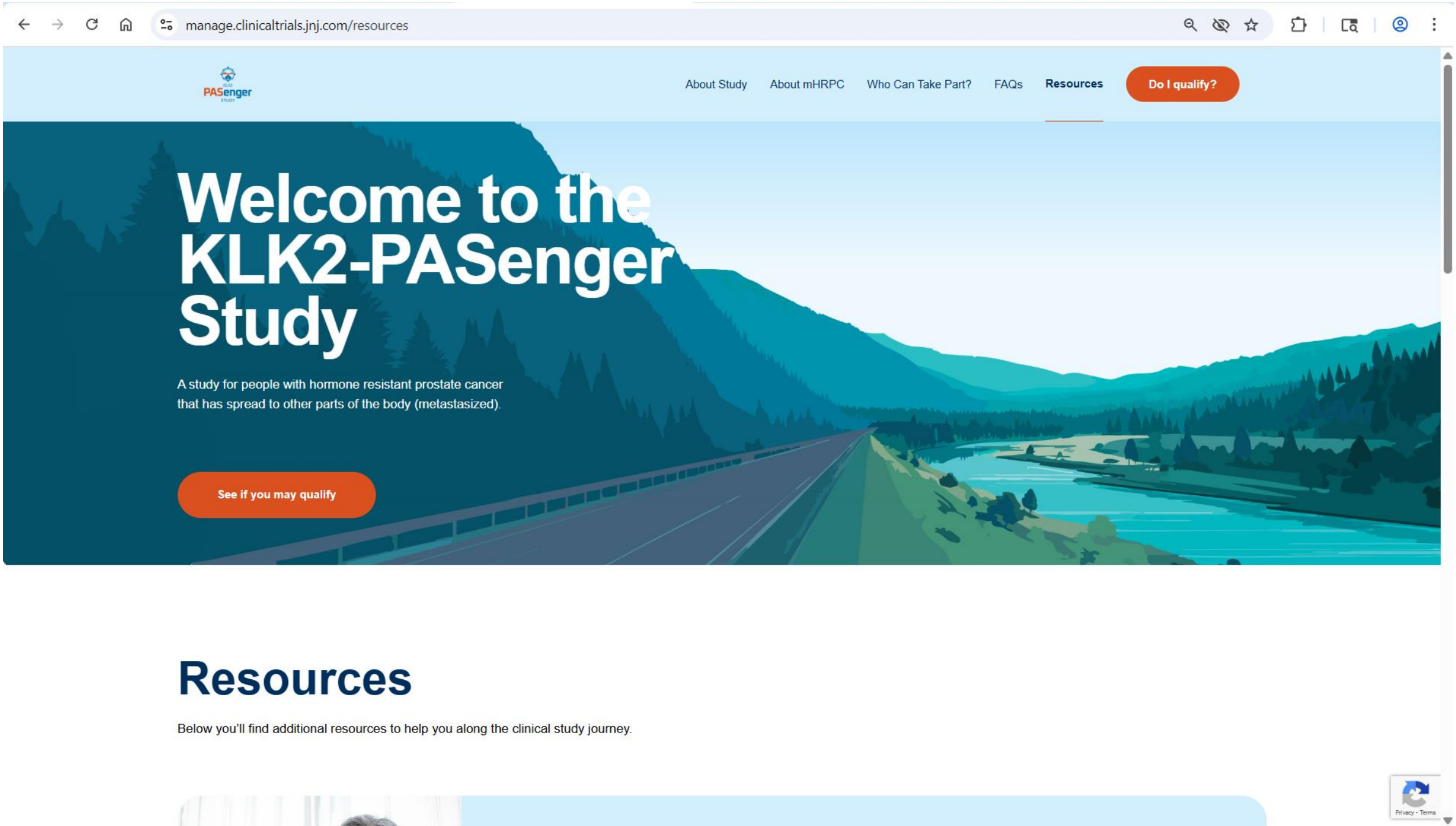

Resources tab

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manage.clinicaltrials.jnj.com/resources

Resources

Below you'll find additional resources to help you along the clinical study journey.

Explore ongoing clinical studies

Stay informed about research studies that could be relevant to your health needs.

Find trials

What are clinical trials?

Learn how clinical studies work, why they matter and what to expect if you participate.

Learn more

Research Includes Me

Resources tab

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Learn more

Research Includes Me

Advances in medicine are possible when we listen to every voice. Find out why including everyone is important.

Learn more

See if you may qualify

Answer the following questions to see if you or someone you know may be eligible to take part in this study.

1. Are you a US resident?

1 / 6

Next >

Privacy - Terms

Resources tab

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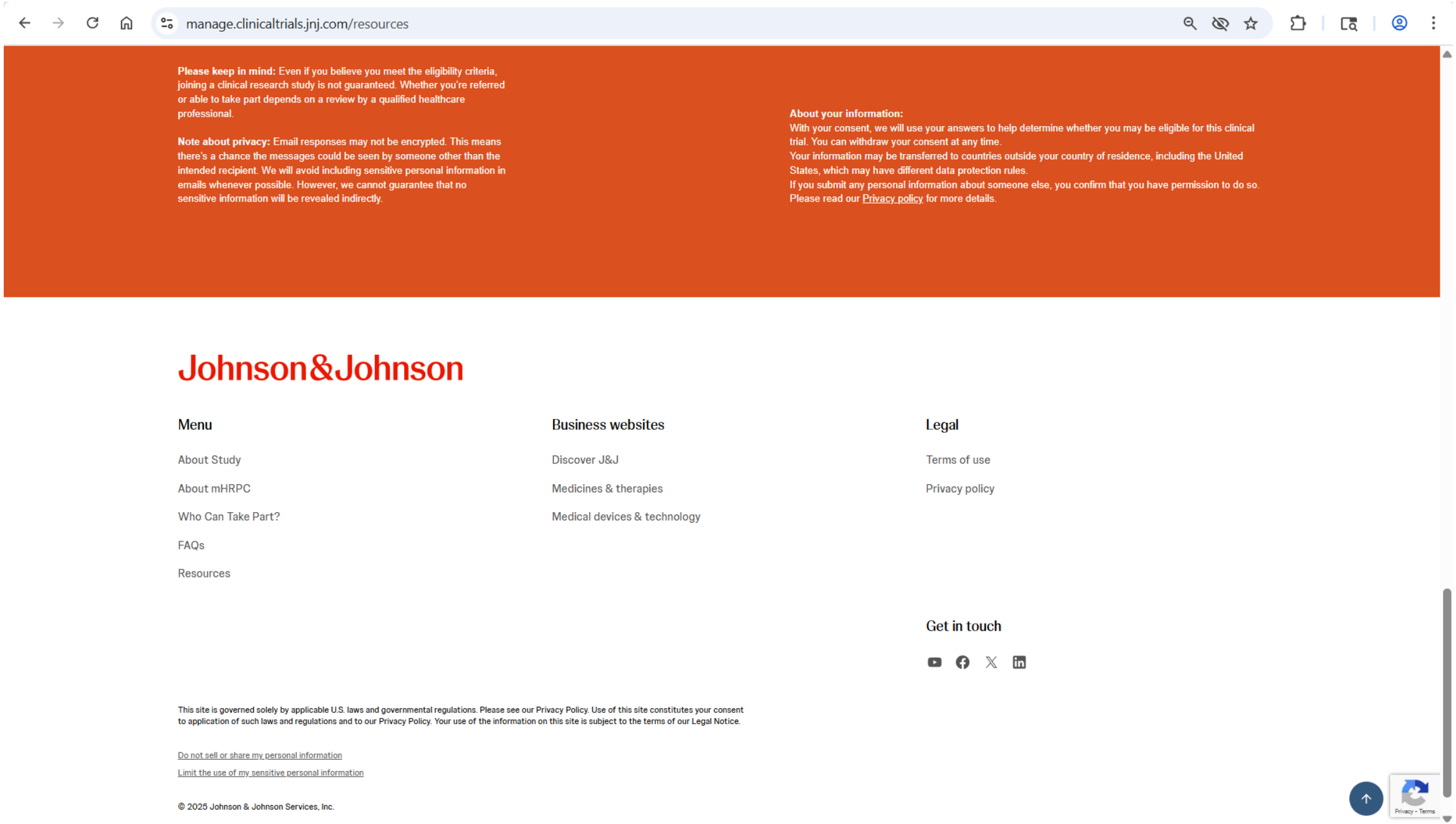

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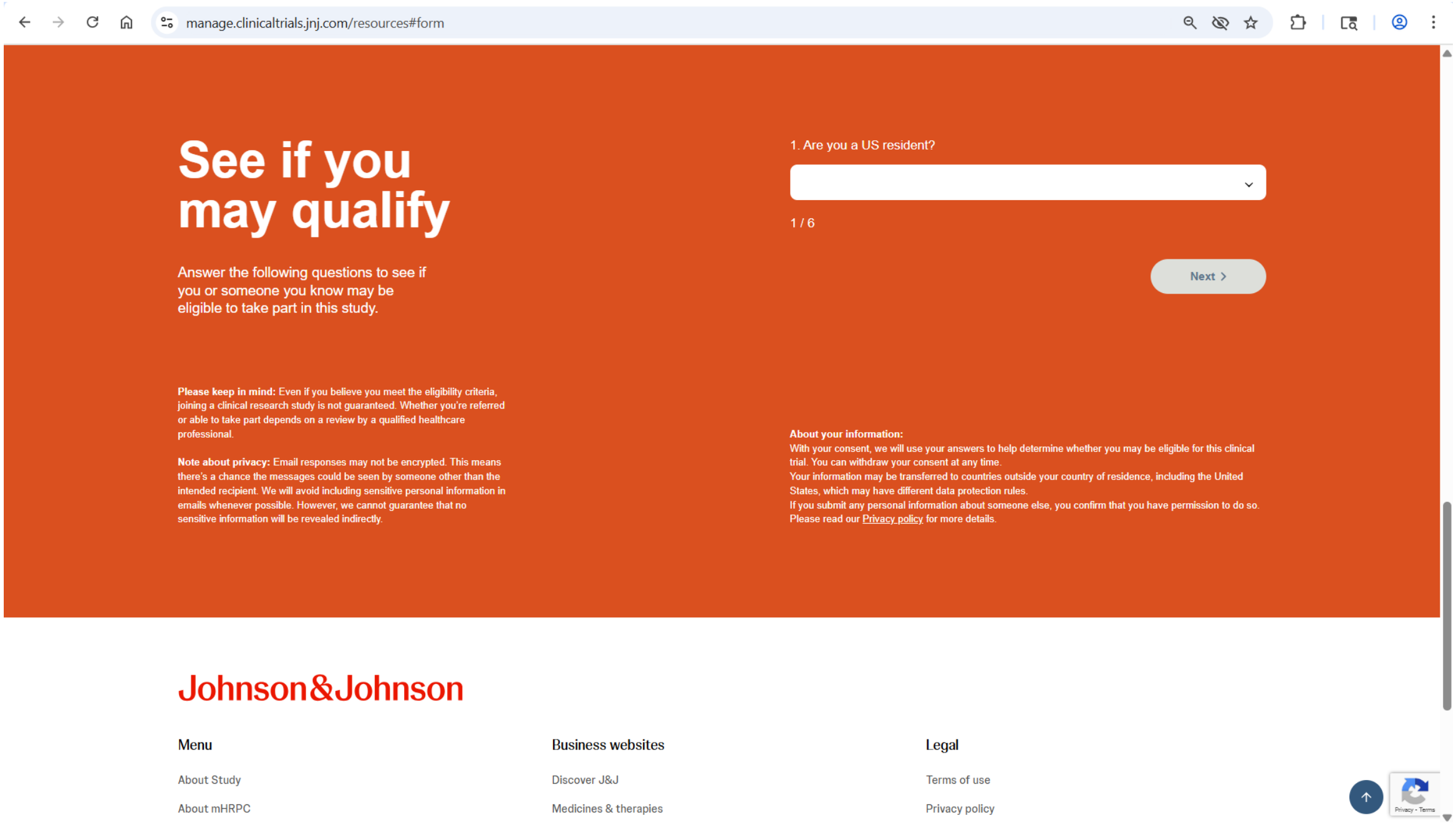

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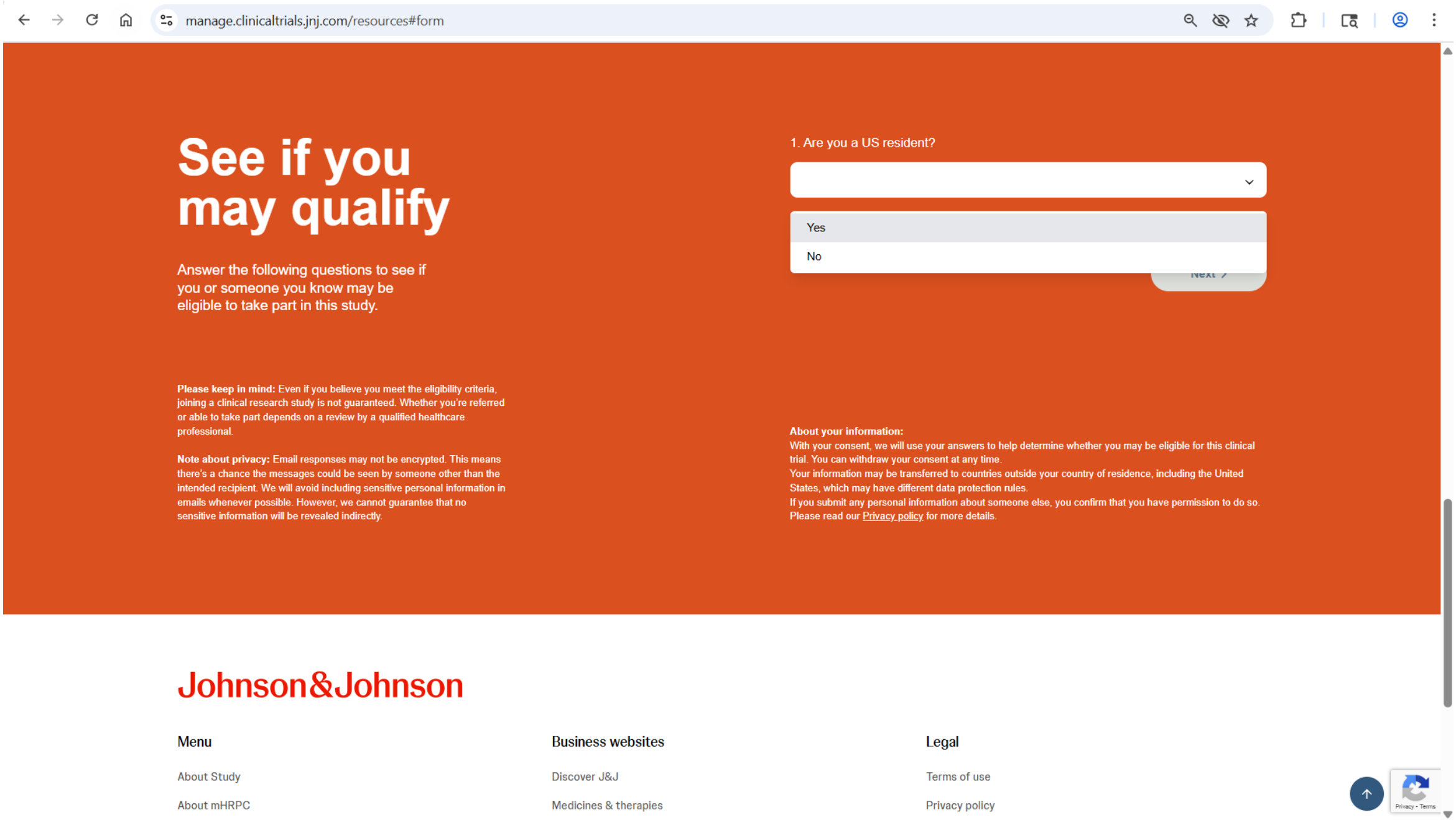

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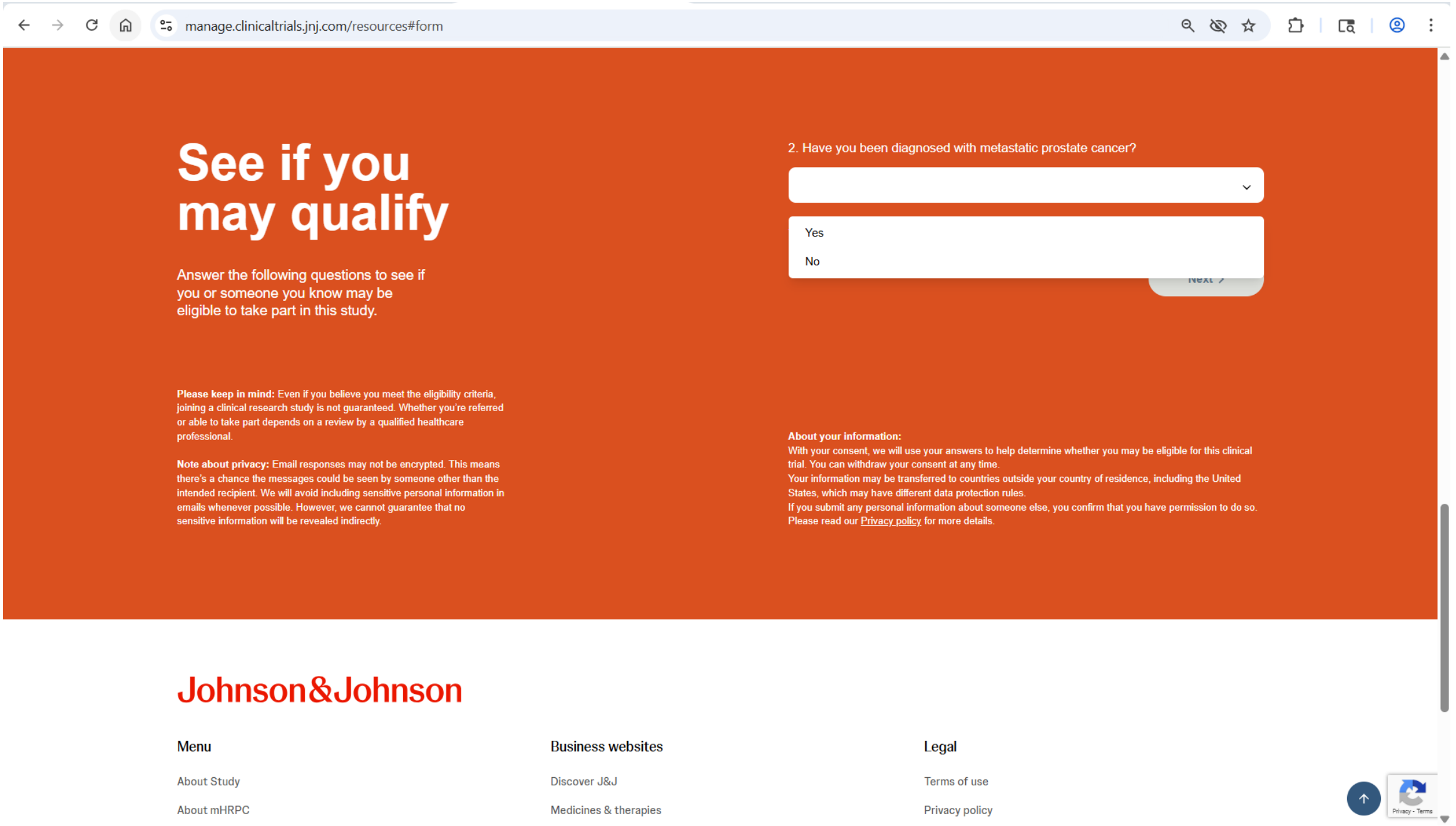

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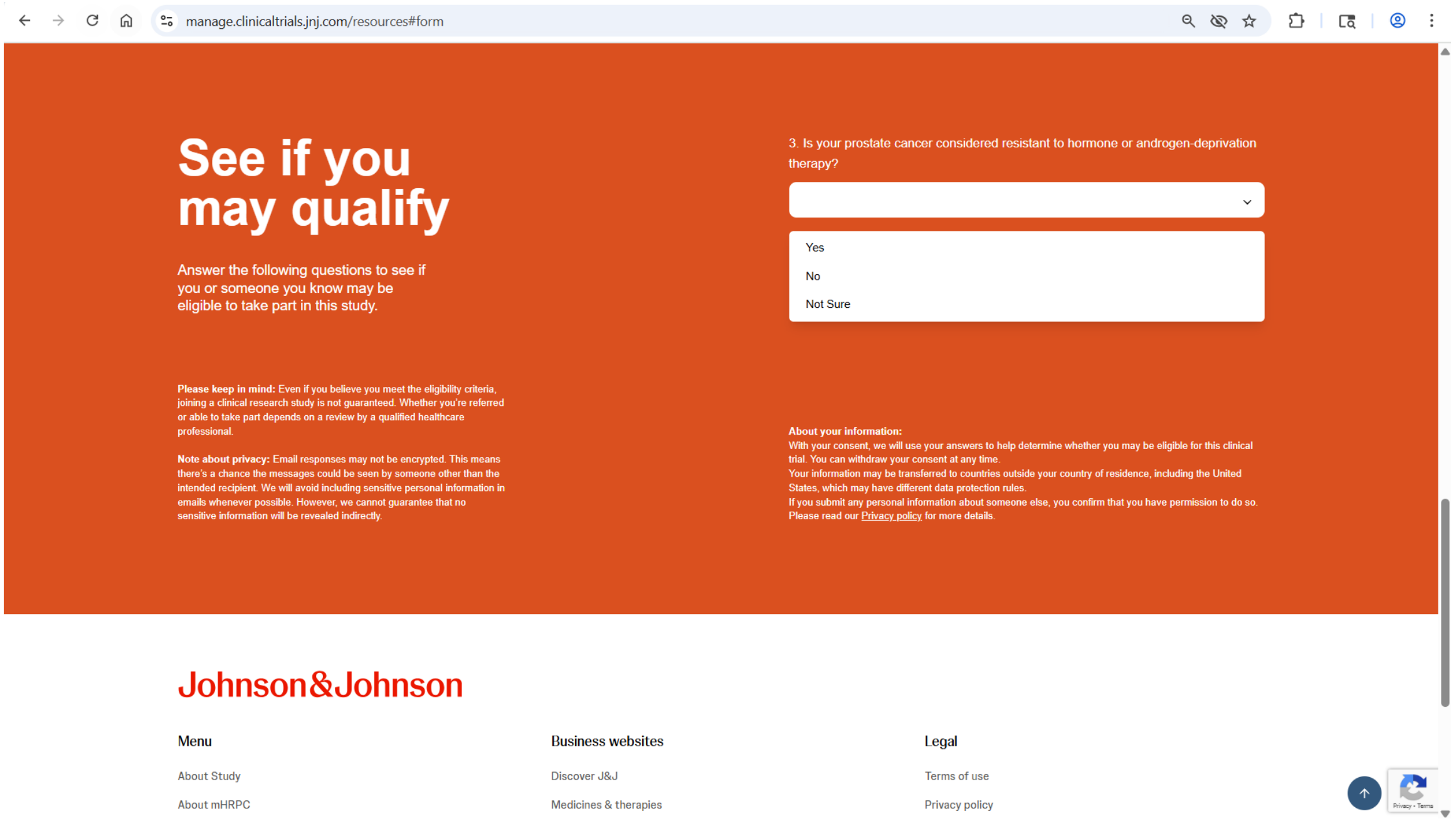

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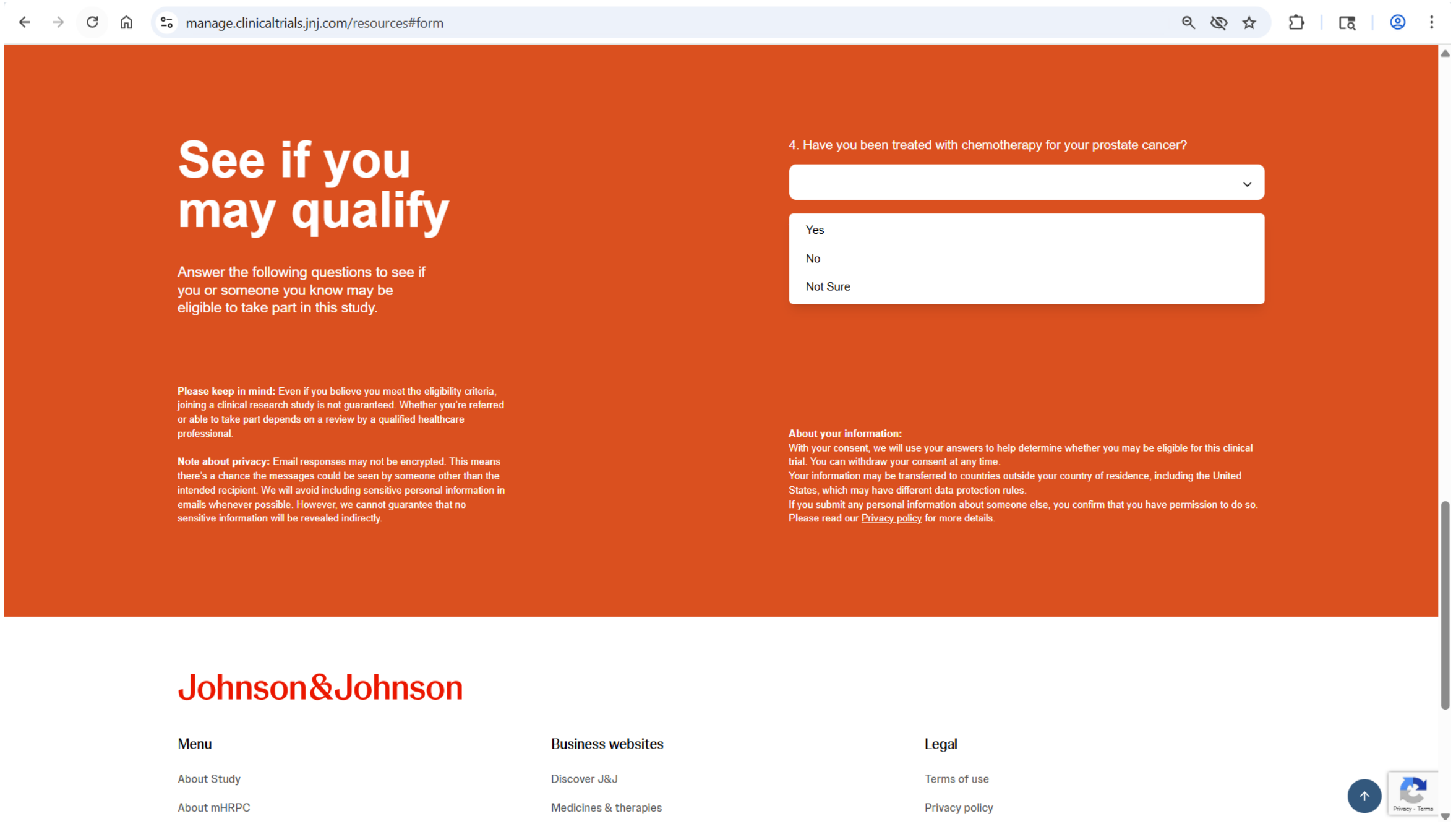

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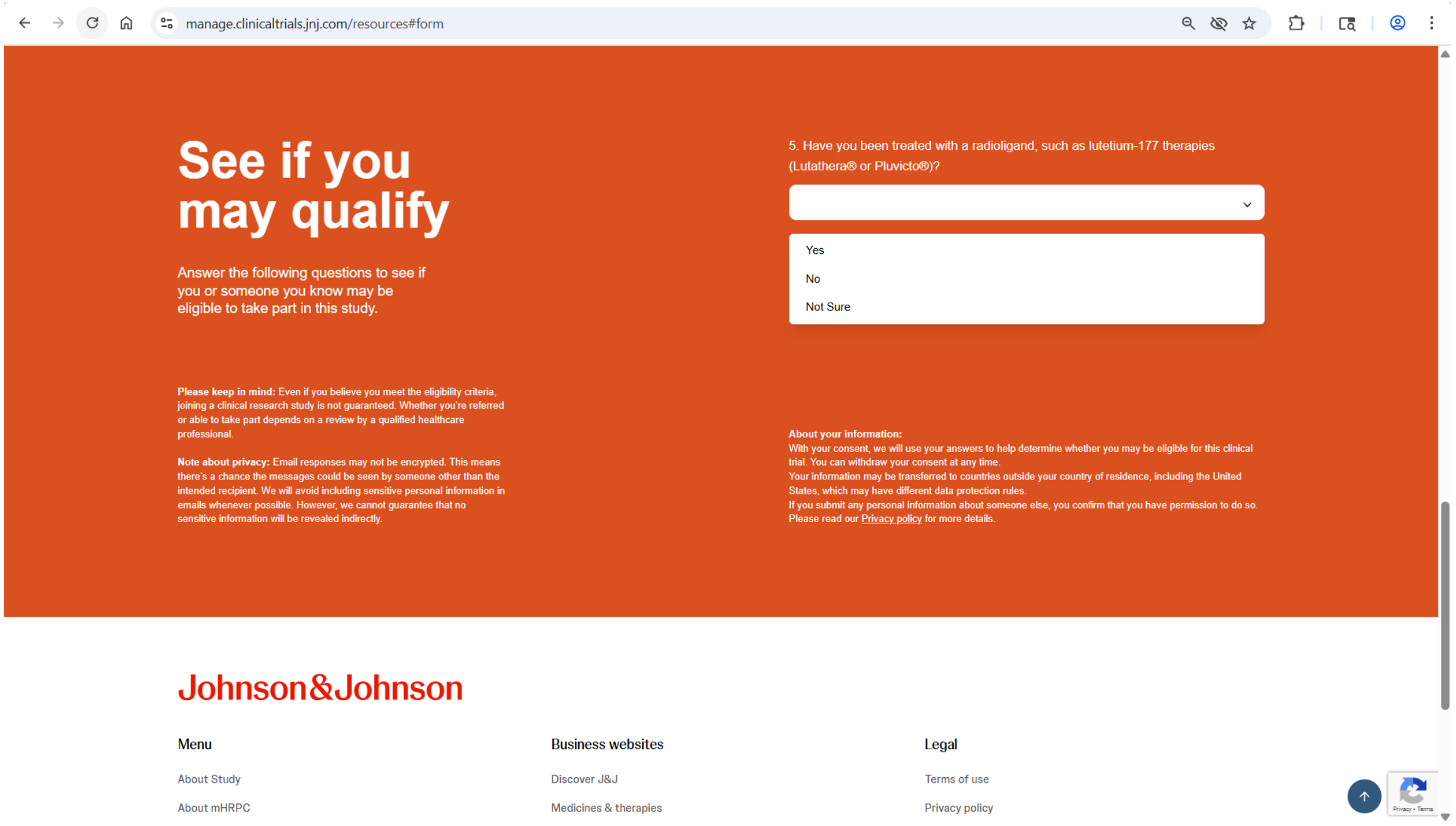

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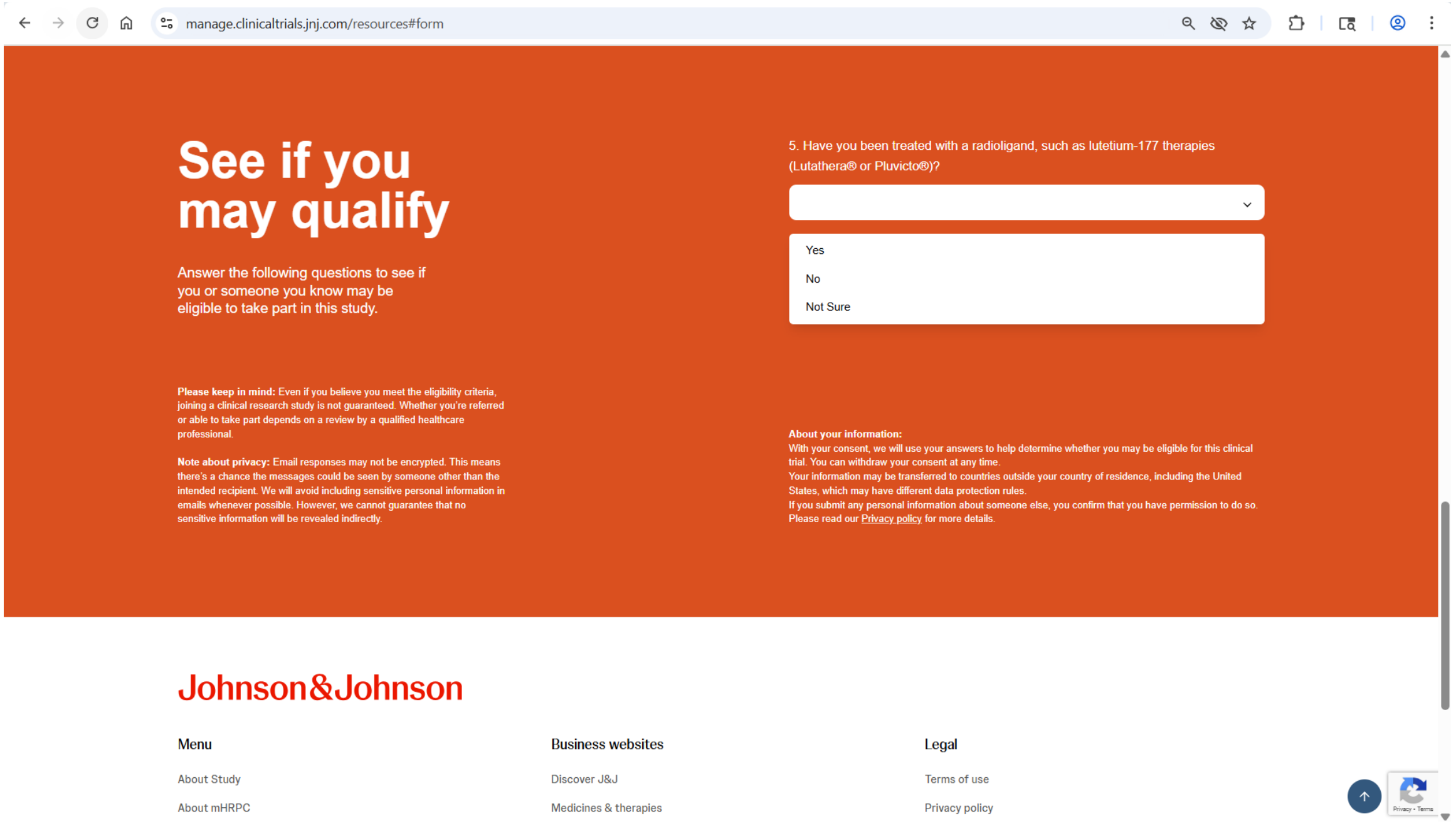

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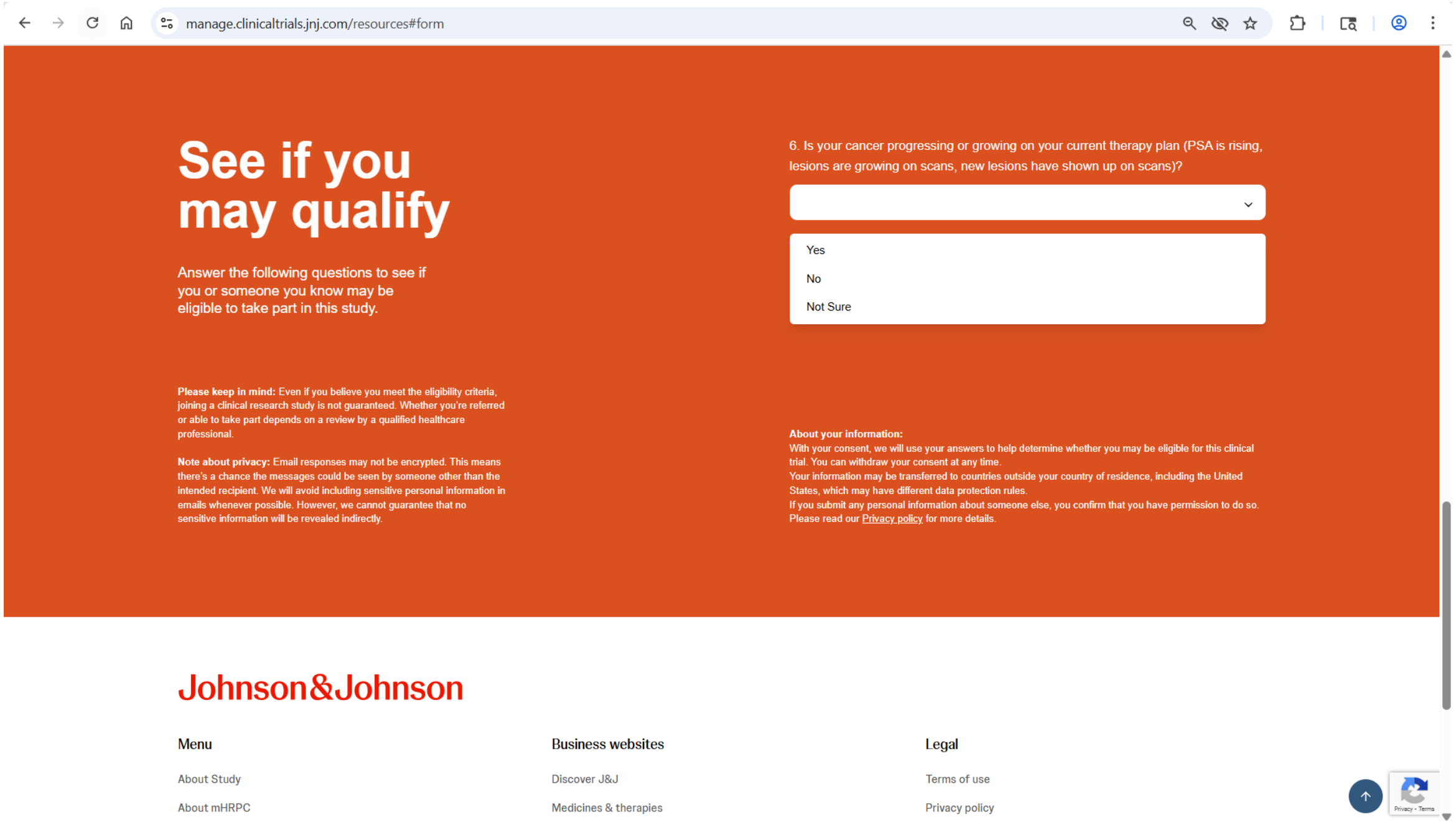

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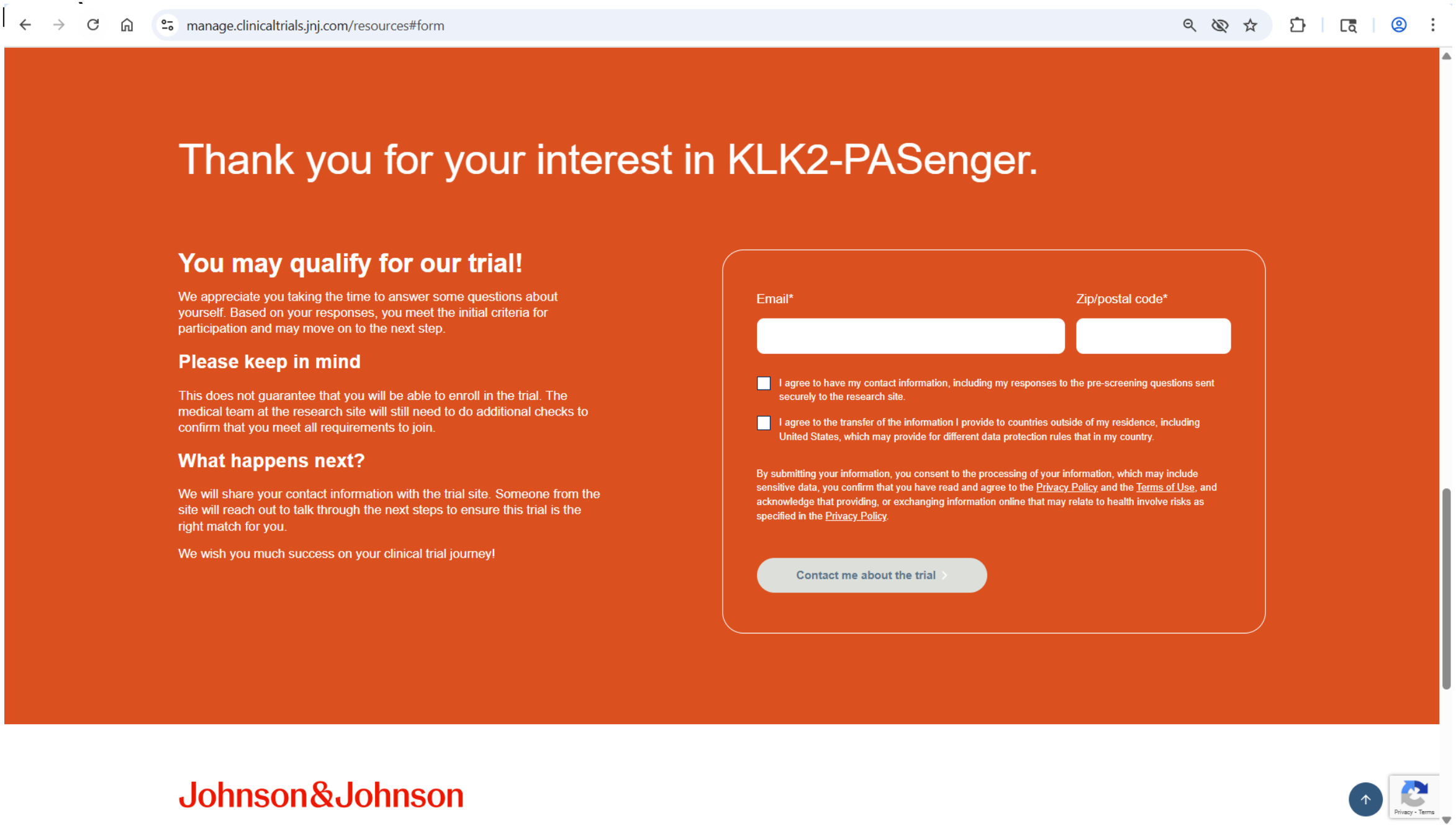

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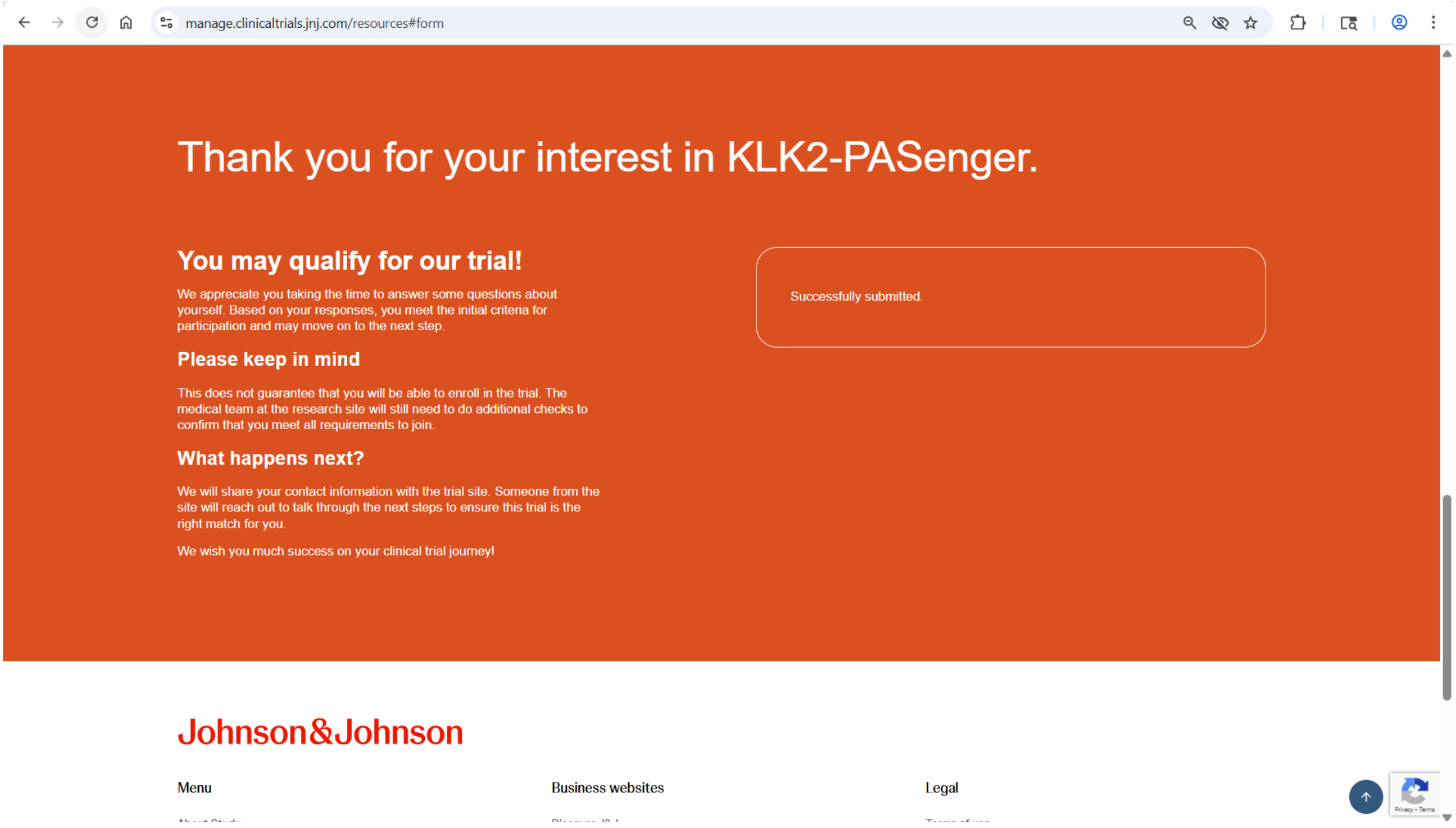

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NEGATIVE: Pre-screener button (Nav Bar, Hero across all pages, anywhere “See if you may qualify” button appears)

Link to Trial search on JJCT main website