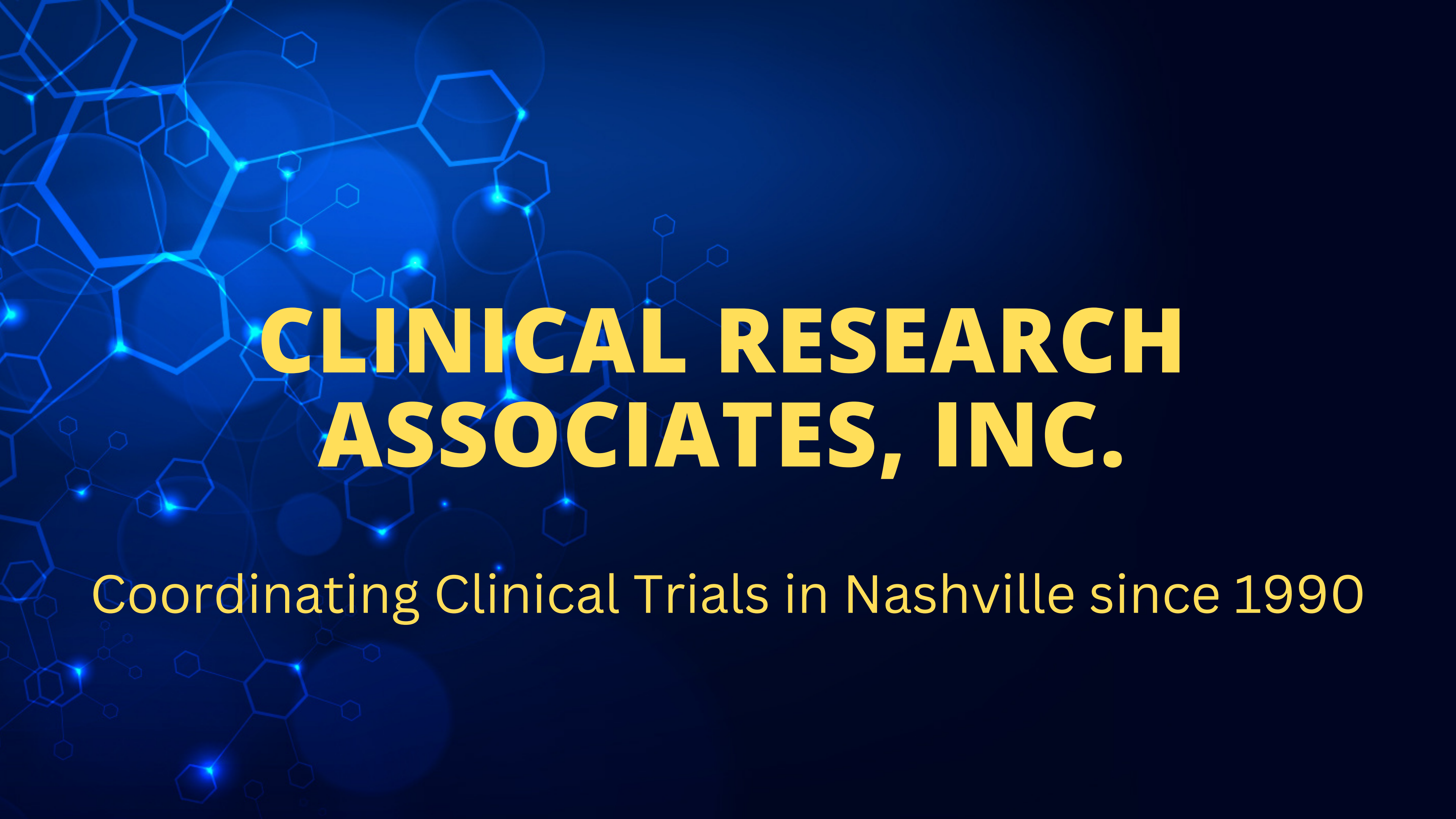


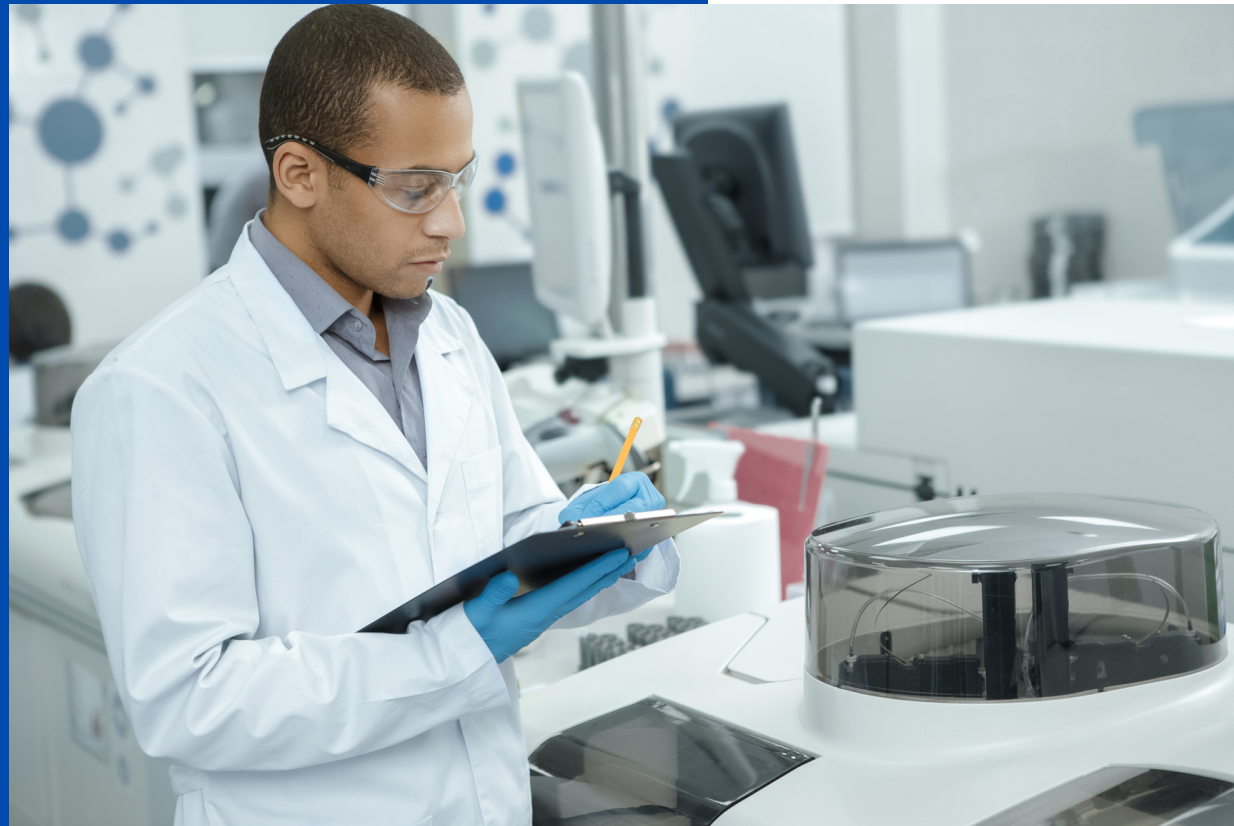


CLINICAL RESEARCH ASSOCIATES, INC.

Coordinating Clinical Trials in Nashville since 1990

UNDERSTANDING CLINICAL TRIALS ➔

What is the purpose?



- **Clinical Trials study how humans react to investigational medicines and devices, so that we can know if they are safe and effective for everyone.**
- **Clinical trials must include a representative picture of the populations and communities impacted by the clinical conditions being studied.**



WHAT DO CLINICAL TRIAL SITES LIKE CRA DO?



Pictured: A CRA patient receives the first approved COVID-19 vaccine in Tennessee in late 2020

1) Find patients who may be affected by a medical condition in a geographic area, and ask if they would consider volunteering for a clinical trial.

2) Conduct clinical trials that **ABOVE ALL ELSE** protect the safety, health, and human rights of patients at all times.

3) Help answer a medically relevant question. For example, does a vaccine provide adequate protection compared to a placebo?



CLINICAL TRIAL SAFETY AND PROGRESSION ➔

Three Phases, or Hurdles for Safety

Phase 1

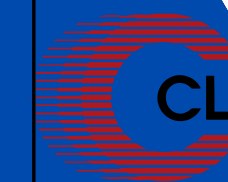
- <100 volunteers
- Can the body tolerate the investigational product?
- Safety is the primary outcome

Phase 2

- A few hundred to a few thousand volunteers
- What is the appropriate dosing size?
- How does the body respond to the investigational product?

Phase 3

- Thousands of volunteers across many geographies
- Does the product achieve its intended purpose?
- Does the product reduce the severity of disease?



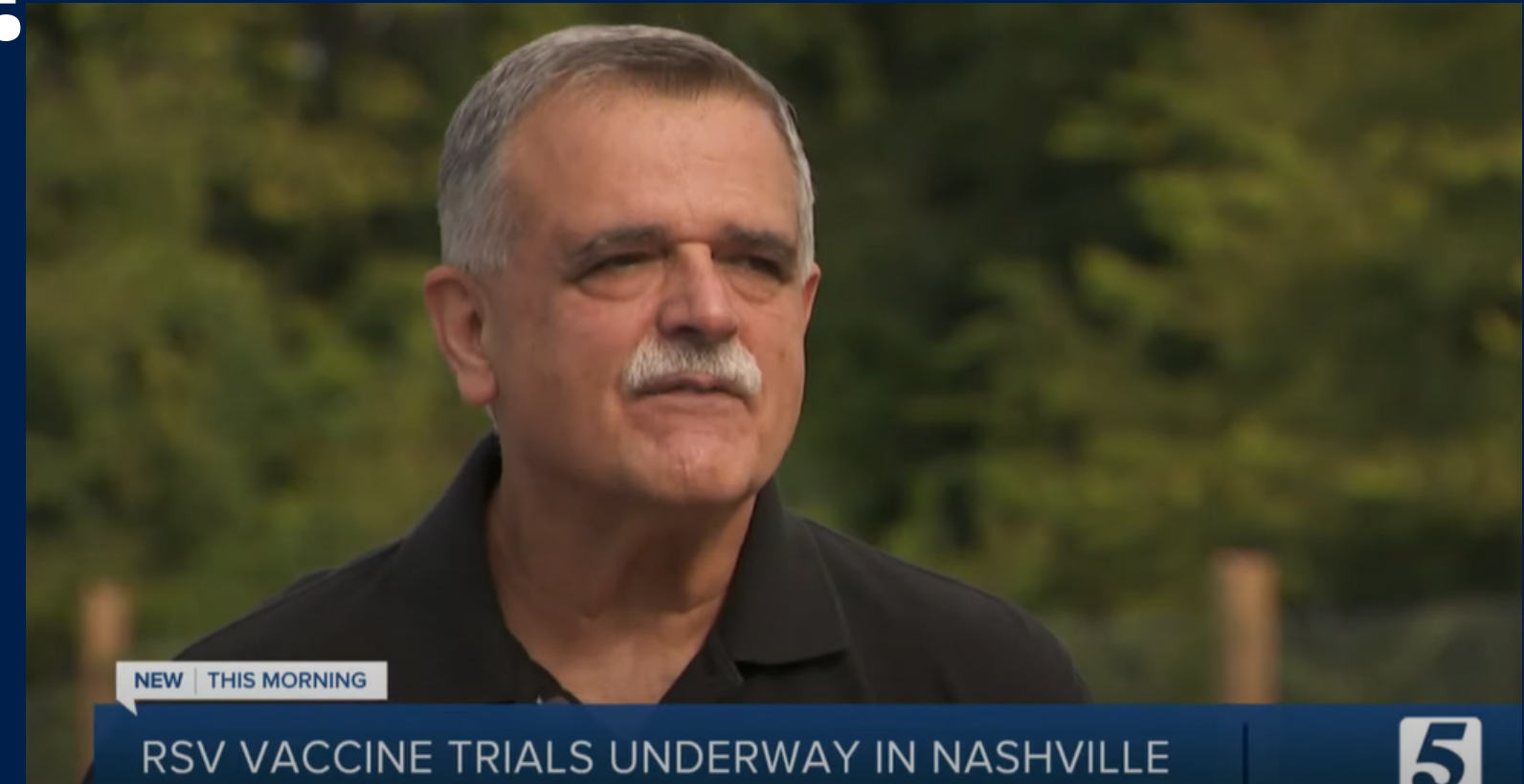
WHO CAN PARTICIPATE?

Anyone who is healthy and well-managed on medications may be eligible to participate in most studies.

Requirements for study participation vary widely depending on what the study is trying to prove.

Each study has unique requirements, but people from all backgrounds are encouraged to participate.

Patients can represent both themselves and their community through participation



A CRA patient discusses his experiences in a clinical trial for RSV vaccines with Nashville News Channel 5

WHO SHOULD SIT OUT?



Some patients with pre-existing conditions or who take certain medicines may be excluded for their safety.

A trial coordinator or patient recruiter will carefully discuss the **inclusion and exclusion criteria** before a patient joins.

Patient health and safety is the most important deciding factor.





CLINICAL TRIALS RELY ON VOLUNTEERS

It's a patient's choice to join a study, and they should take their time to decide.



Patients have an opportunity to review thoroughly the potential risks, benefits, and events with health professionals during the **informed consent** process.

If they decide to join:

- They can leave **whenever** they want.
- They can leave **for any reason** they want.



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PATIENT RIGHTS AND SAFETY

There are many layers of patient protections, from federal government oversight and regulations to independent organizations and ethical review boards.

The global medical community has formed rules for conducting clinical trials enforced by federal laws.

- The **Nuremburg Code** of 1947
- The **Declaration of Helsinki** in 1964
- The **Belmont Report** in 1978



WHY IS PARTICIPATION IN RESEARCH IMPORTANT?



Everyone is unique, so it matters to have representation from people of a variety of ages, genders, races, ethnicities, nationalities, and health histories to participate.

This way, researchers can learn how medicines and devices impact the population at large.

We learn if and how medicine impacts people differently through clinical trials

How do Patients Benefit From Joining a Clinical Trial?

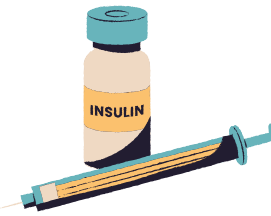
Clinical studies' primary benefit is from information which will help future generations. Individual patients may not directly benefit from the drug or device being studied. However, there may be other advantages from participating in a clinical study, including:

- **Study-related care:** some studies provide additional healthcare to patients, like diet and exercise coaching.
 - **24/7 access** to discuss serious health issues.
 - **Compensation** is provided to offset travel, time-off, or childcare expenses.

CURRENT AND UPCOMING CLINICAL TRIALS AT CRA



Combination Flu/COVID Vaccines



**Diabetes, Cardiovascular, Weight Loss,
and Glucose Management Studies**



Migraines



RSV Vaccines (Pediatric)



Heartburn/Acid Reflux



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FLU/COVID COMBINATION STUDY

Short enrollment period between Feb. 23 and 29



This study evaluates the safety and efficacy of a combination of COVID and Flu vaccines in a single injection, compared to each in single doses.

The combination could increase the likelihood of higher vaccination rates for both viruses, due to increased convenience.

Anyone age 50-and-over who has not had a flu or COVID shot within 6 months may qualify.

DIABETES, CARDIOVASCULAR ISSUES, WEIGHT LOSS, & GLUCOSE CONTROL

We are evaluating the next generation of GLP-1 analog drugs like Ozempic and Mounjaro in several unique studies.

Participants with a wide range of health conditions may be able to enroll.

We recommend anyone interested should sign up for a pre-screening call on our website, or call us at (615) 329-2222 to speak with our team or to ask questions.



MIGRAINE TREATMENT



This is a comparative study for two migraine treatments that have already been approved by the FDA. All patients in the study will receive active medicine.

Patients must have monthly migraine attacks, and there is no placebo group in this study.

HEARTBURN AND ACID REFLUX

This study aims to evaluate the safety and effectiveness of a research medication for treating heartburn and acid reflux. This medication is approved for use in several countries outside of the United States.

Patients must experience heartburn several times per month and be willing to undergo an endoscopic exam.



PEDIATRIC RSV VACCINES



We will soon begin new studies for RSV vaccines for infants under 2-years-old. We expect to begin these studies in early 2024.

To stay up-to-date on all of our clinical trials, sign up for our email updates at www.ClinicalResearchAssociates.com/Welcome

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