



Essentials of Study Design

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Research Essentials

11/5/2019



**Groundbreaking
Research?**



PICO





ANDROMEDA-SHOCK

NEXUS CRITERIA





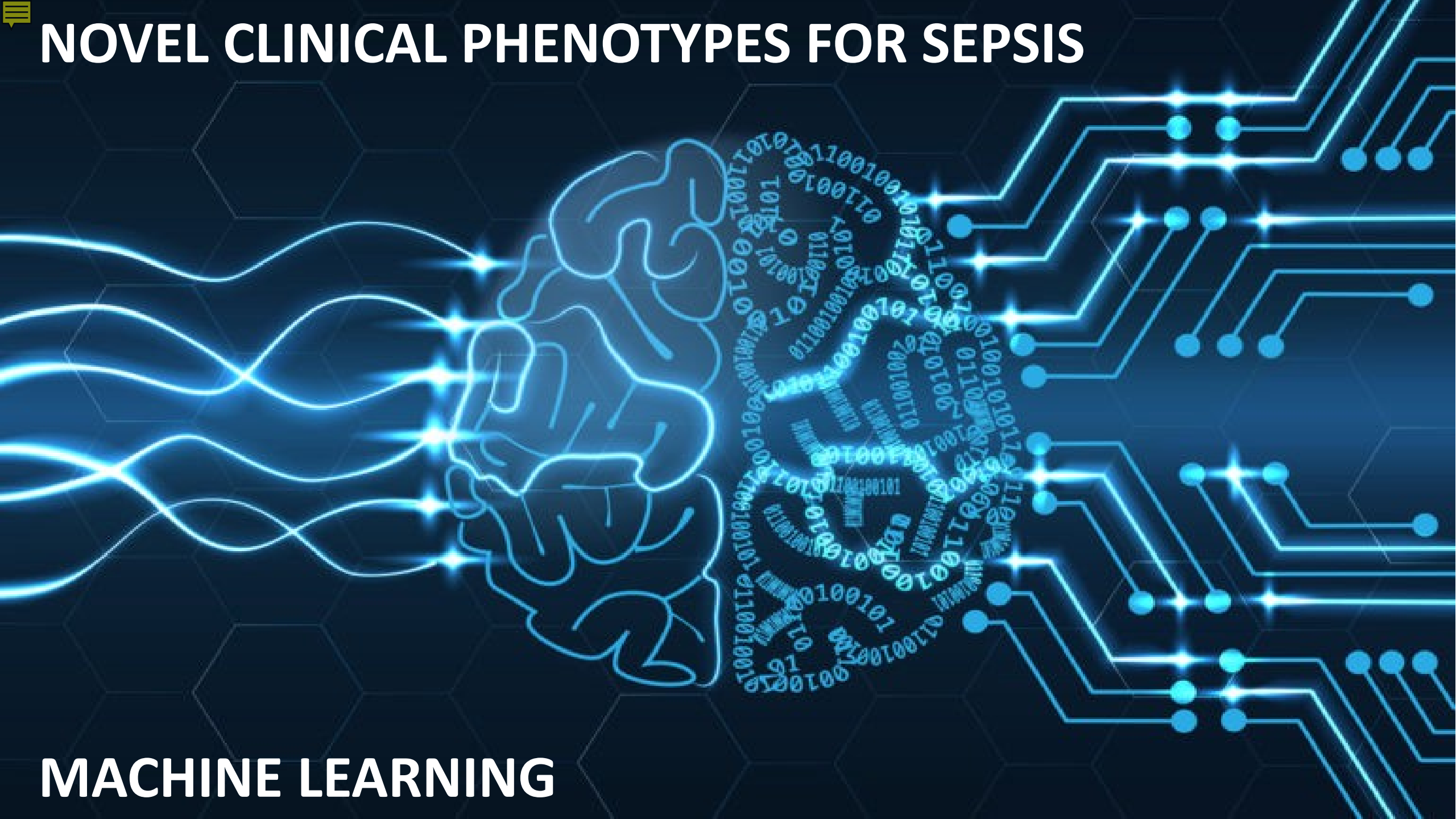
SALT-ED

SMART



equipoise

NOVEL CLINICAL PHENOTYPES FOR SEPSIS



MACHINE LEARNING



Clinical Question



Are CT scans better than X-rays in trauma patients?





Are CT scans better than
X-rays in trauma patients?

P = Trauma Patients



Are CT scans better than X-rays in trauma patients?

I = CT Scans



Are CT scans better than X-rays in trauma patients?

C = X-rays



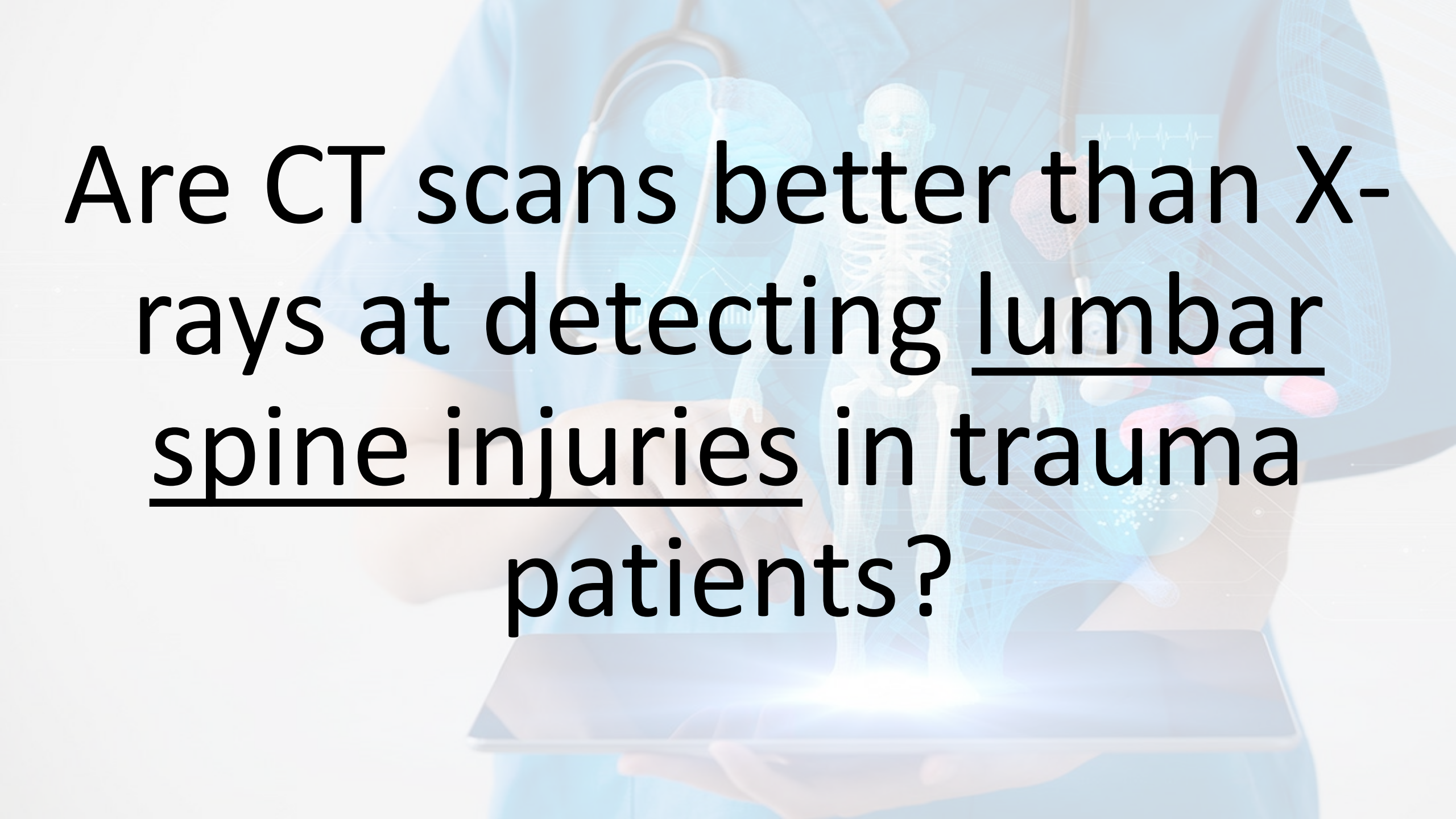
Are CT scans better than X-rays in trauma patients?

0 = ?

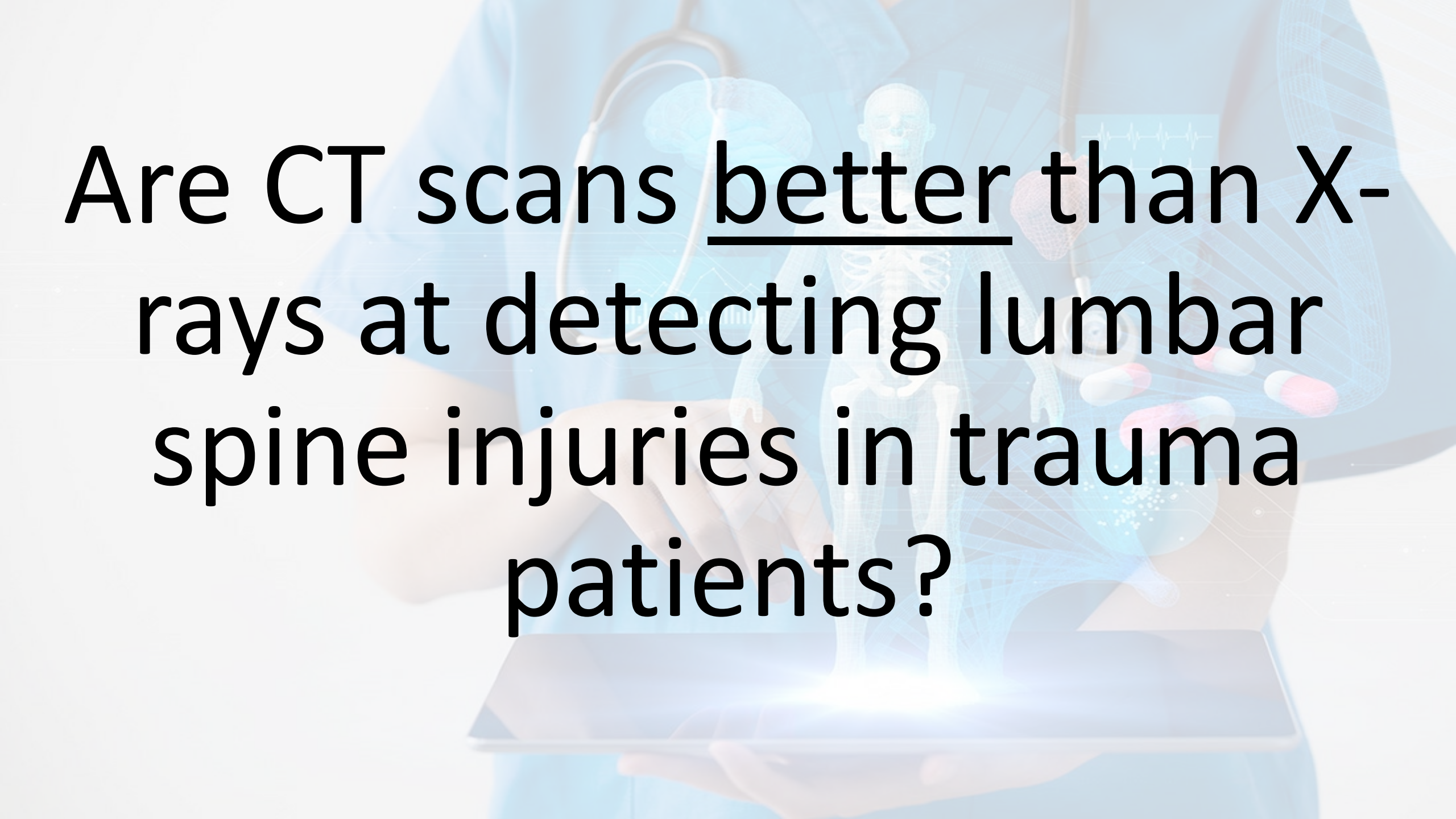


How can we refine this question?

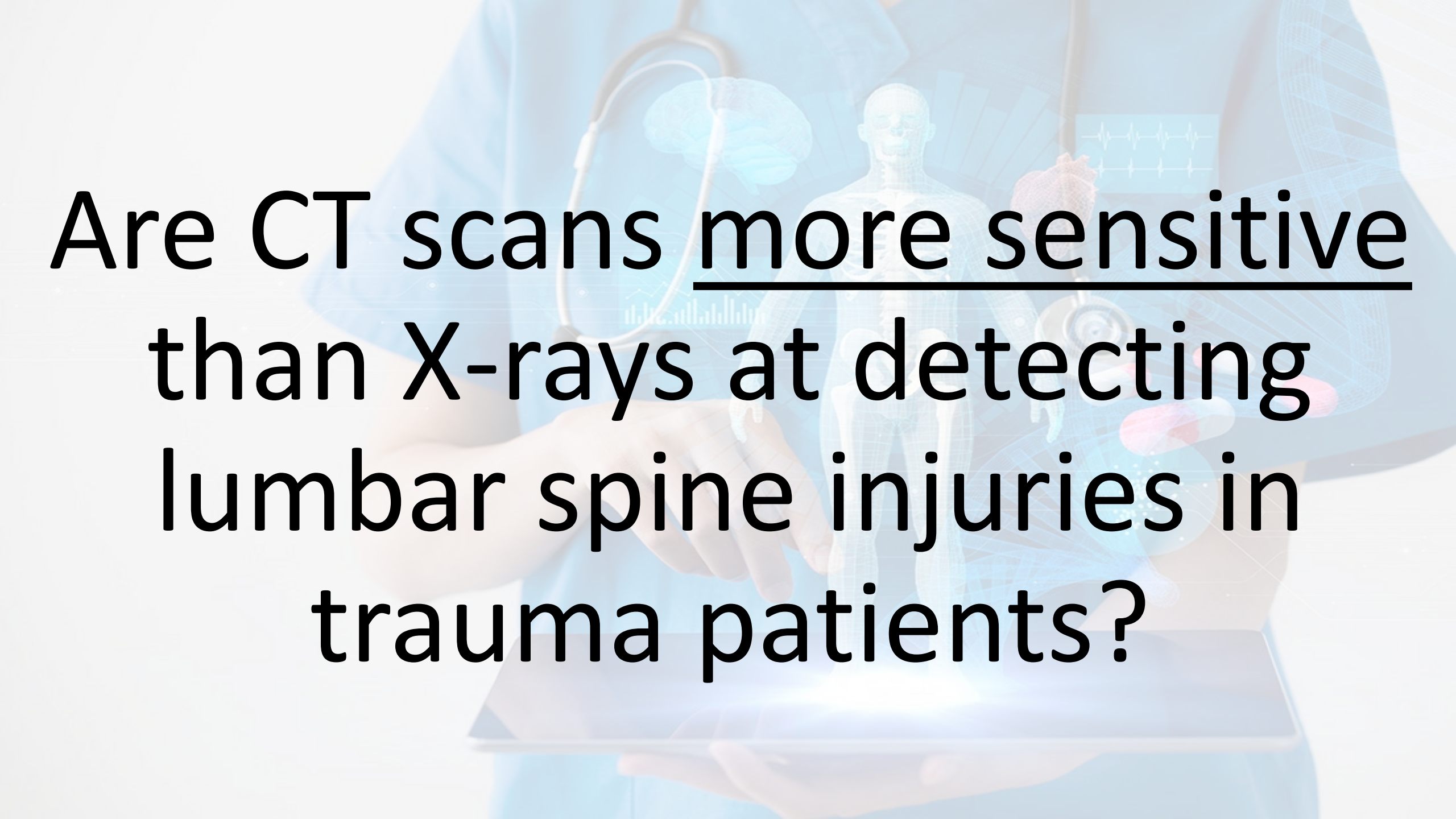




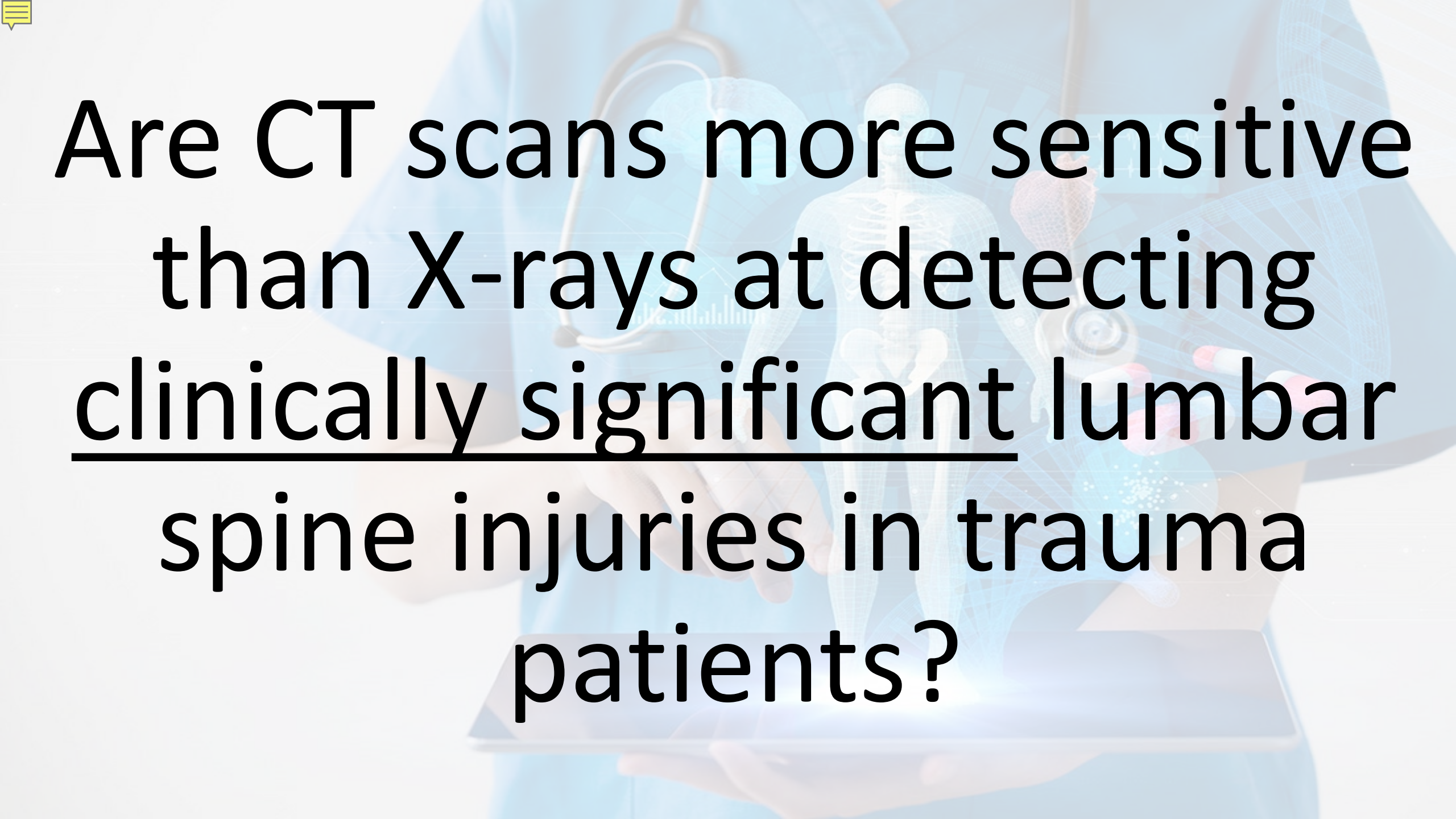
Are CT scans better than X-rays at detecting lumbar spine injuries in trauma patients?



Are CT scans better than X-rays at detecting lumbar spine injuries in trauma patients?



Are CT scans more sensitive
than X-rays at detecting
lumbar spine injuries in
trauma patients?



Are CT scans more sensitive than X-rays at detecting clinically significant lumbar spine injuries in trauma patients?

The background is a dark blue, semi-transparent overlay on a photograph of a person in medical scrubs. The person is holding a tablet. Overlaid on the image are various medical and scientific icons: a stethoscope, a human skeleton, a brain, a DNA double helix, a heart, a hand holding pills, and a pulse line. The text is white and bold.

H_1 : Alternative Hypothesis

H_0 : Null Hypothesis

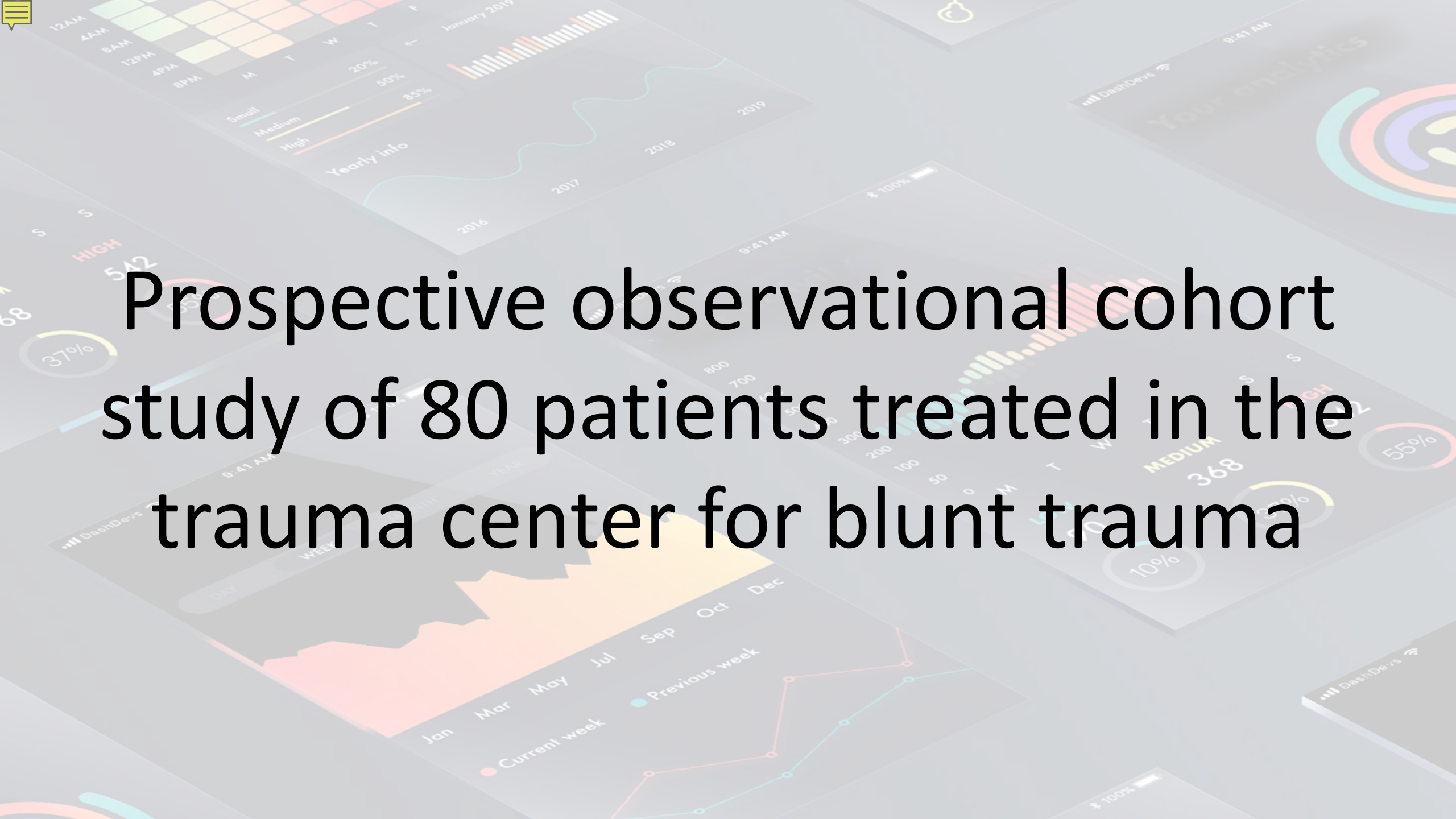


H_1 : CT is better than X-ray

H_0 : CT is not better than X-ray



Types of Error



Prospective observational cohort study of 80 patients treated in the trauma center for blunt trauma



CT is 99% sensitive for CS L-spine injury

X-ray is 85% sensitive for CS L-spine injury



CT is 99% sensitive for CS L-spine injury

X-ray is 85% sensitive for CS L-spine injury

P = 0.09

What conclusion can we make?



Types of Error

Type I = α
Type II = β



Types of Error

α = Type I error rate

$p = 0.05$



Types of Error

β = Type 2 error rate
0.10 - 0.20



Types of Error

$$\text{Power} = 1 - \beta$$



Types of Error

Authors conclude that there is **NO significant** difference between CT and X-ray for detecting CS L-spine injury.



BIAS







Bias

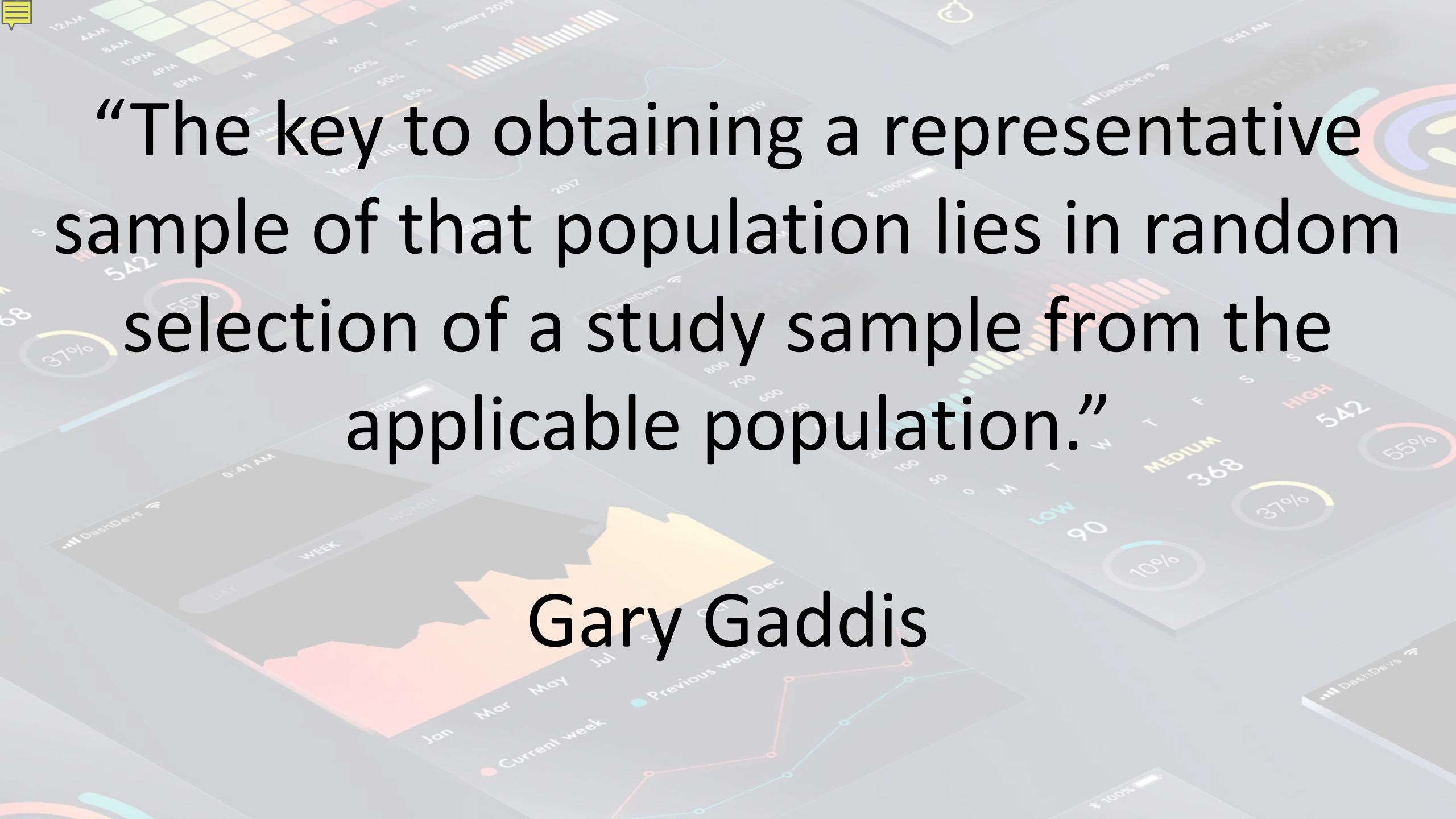
**Enrollment
Implementation
Analysis**

The background consists of several overlapping, semi-transparent dashboard panels. These panels display various data visualizations: a calendar grid with colored cells, a bar chart with a y-axis from 0 to 500, a line graph with a wavy blue line, a circular gauge showing 55%, a map of a region highlighted in yellow, and another bar chart with a y-axis from 0 to 500. The text is overlaid on these panels in a large, bold, black font.

Random Error

Related to sampling variability

Occurs when one deals with a sample of patients instead of the whole population.



“The key to obtaining a representative sample of that population lies in random selection of a study sample from the applicable population.”

Gary Gaddis



Validity

Internal

External

Design Tips

**Utilize our
Librarians**

**Gretchen
Kuntz**



Design Tips

**Assemble
a team**

**Consult
experts early**



Design Tips

Testable
Hypothesis



Design Tips

No one size
fits all



Design Tips

**Utilize CRT
Resources
to gain skills**



Center for Research Training



Research Essentials

**Research Training
Academy**

**Jax
Scholars**

Center for Research Training

**All Faculty, Fellows
Trainees and Staff**

- Study design
- Basic biostats
- Scientific writing
- Networking
- Career forums



Research Essentials

Center for Research Training



Research Training Academy

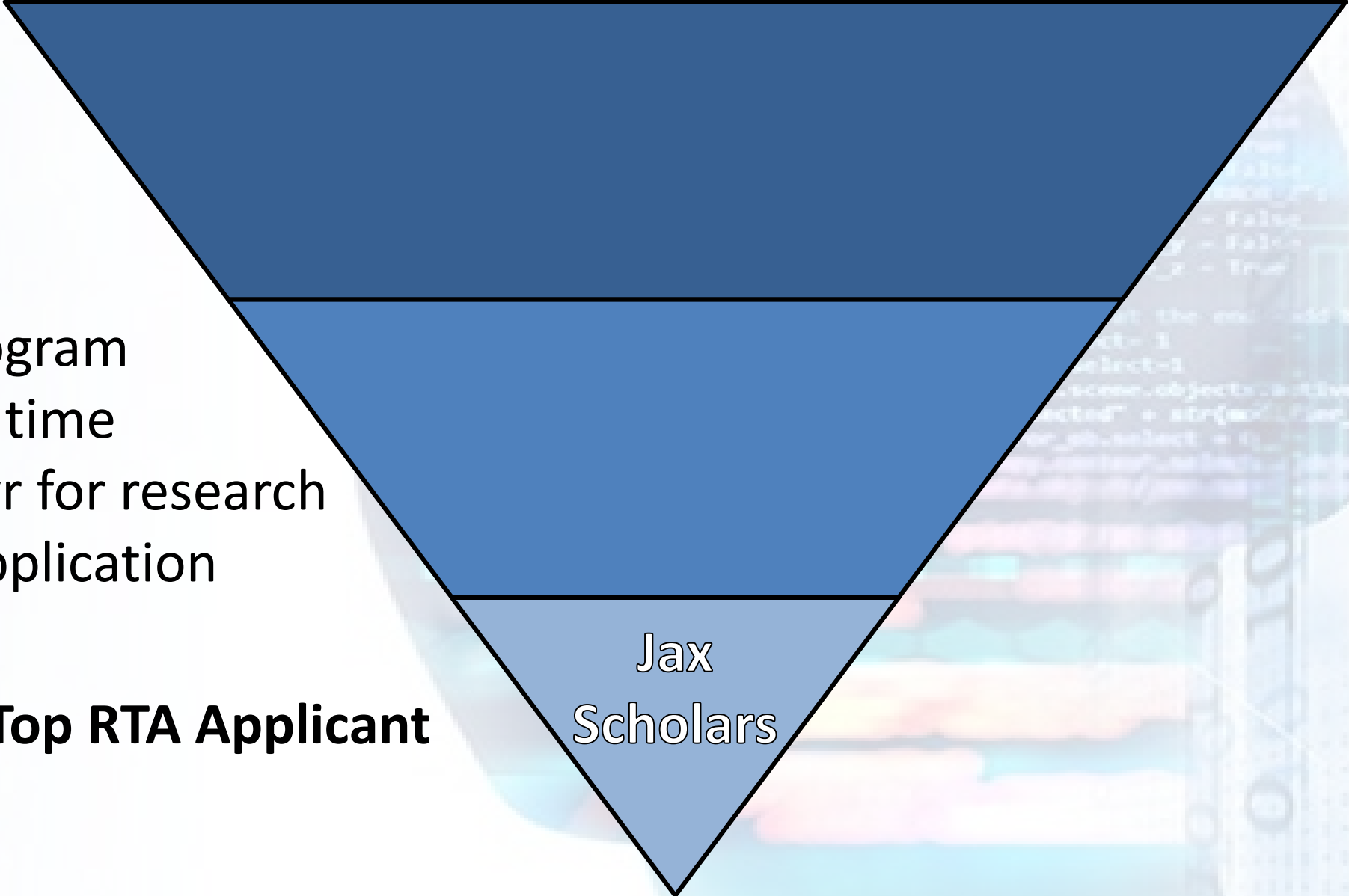
Select Faculty (0.10 FTE)

- In-depth study design
- Grant writing course
- Grant support/funding
- Career coaching
- Mentorship advising

Center for Research Training

- 2-year program
- Protected time
- \$15,000/yr for research
- K Grant application

Top RTA Applicant



Jax
Scholars

CRT

Mini courses
and online
content



```
mirror_mod.use_x = False
mirror_mod.use_y = True
mirror_mod.use_z = False
elif _operation == "mirror_z":
    mirror_mod.use_x = False
    mirror_mod.use_y = False
    mirror_mod.use_z = True

#selection at the end - add 1
mirror_ob.select= 1
modifier_ob.select=1
key.context.some.objects.active =
print("Selected" + str(mirror_ob))
[mirror_ob.select = 1]
key = key.context.select
key.mousebutton/press
```

**Want to learn
more?**

www.CRTJax.com

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