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**CLINICAL TRIALS: SEEKING
CERTAINTY IN AN EXPERIMENTAL
WORLD**

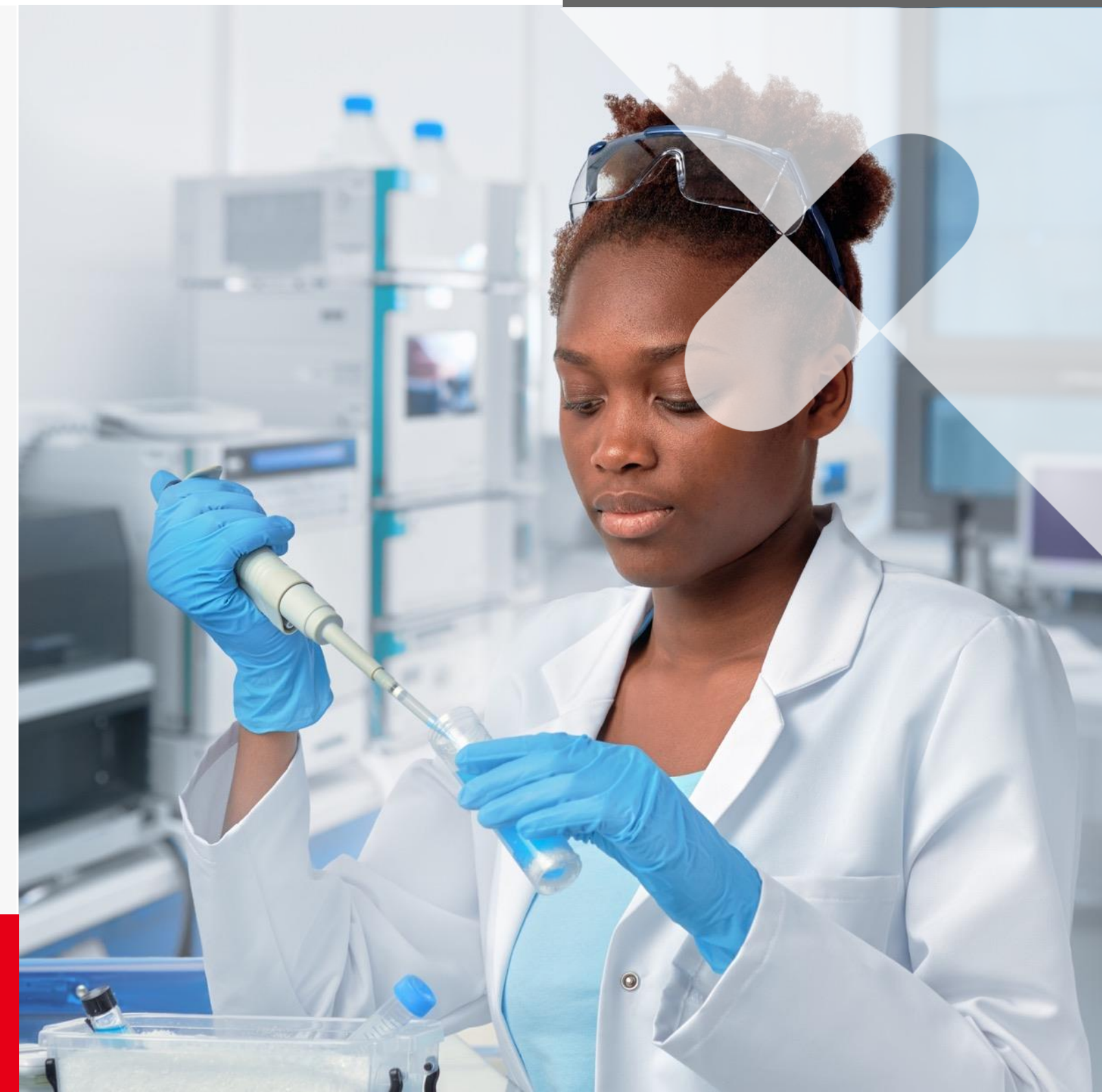
PIONEERING VALUE DRIVEN INSURANCE SOLUTIONS GLOBALLY.



LIFE SCIENCES

Agenda

- Introduction to Clinical Trials
- Commonly Used Terminology
- An Overview of Clinical Trials Insurance and Risk Factors
- Pandemic Risks
- COVID-19 Trial Activity





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Terminology

Roles in a Clinical Trial

Documents

Protocol

Informed Consent Form (ICF) / Patient Informed Consent (PIC)

Phases of Clinical Research/Types of Trial

Phase I: Possibly a First-in-human

Phase II/Phase III

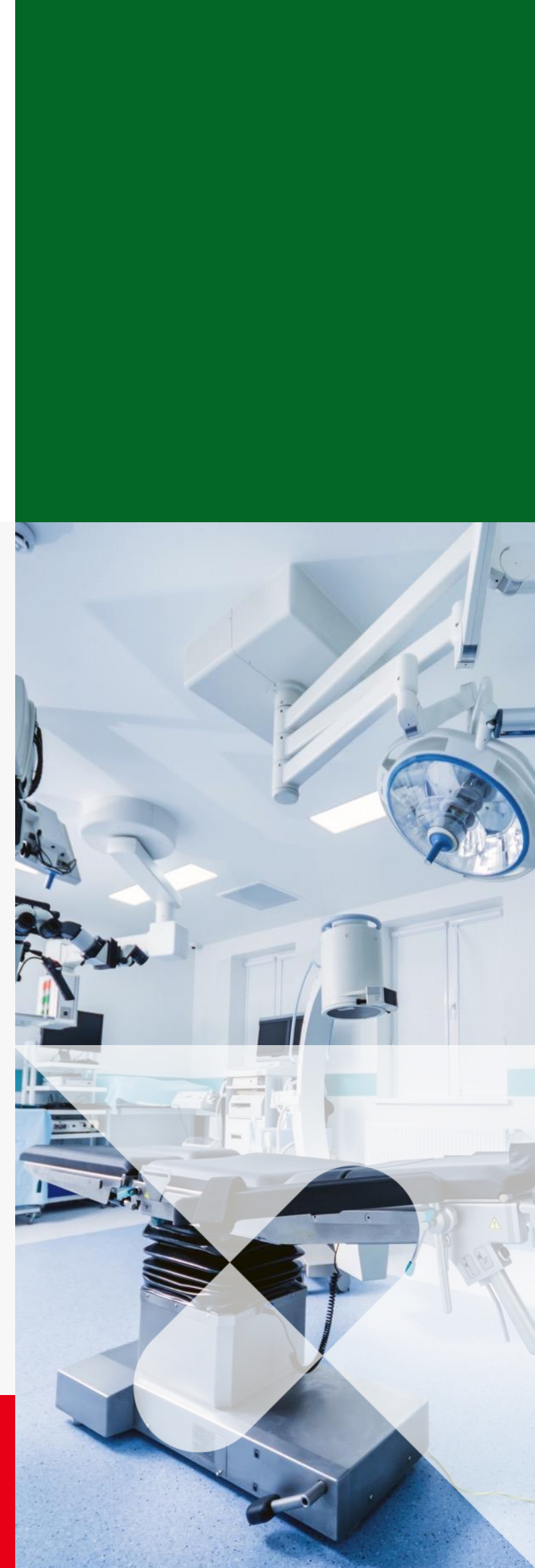
Phase IV: Post Market Surveillance

Observational Trials: Pure data collection

Bioequivalence: Comparison of an unapproved product to an identical approved product.

Screened vs. Enrolled Patients

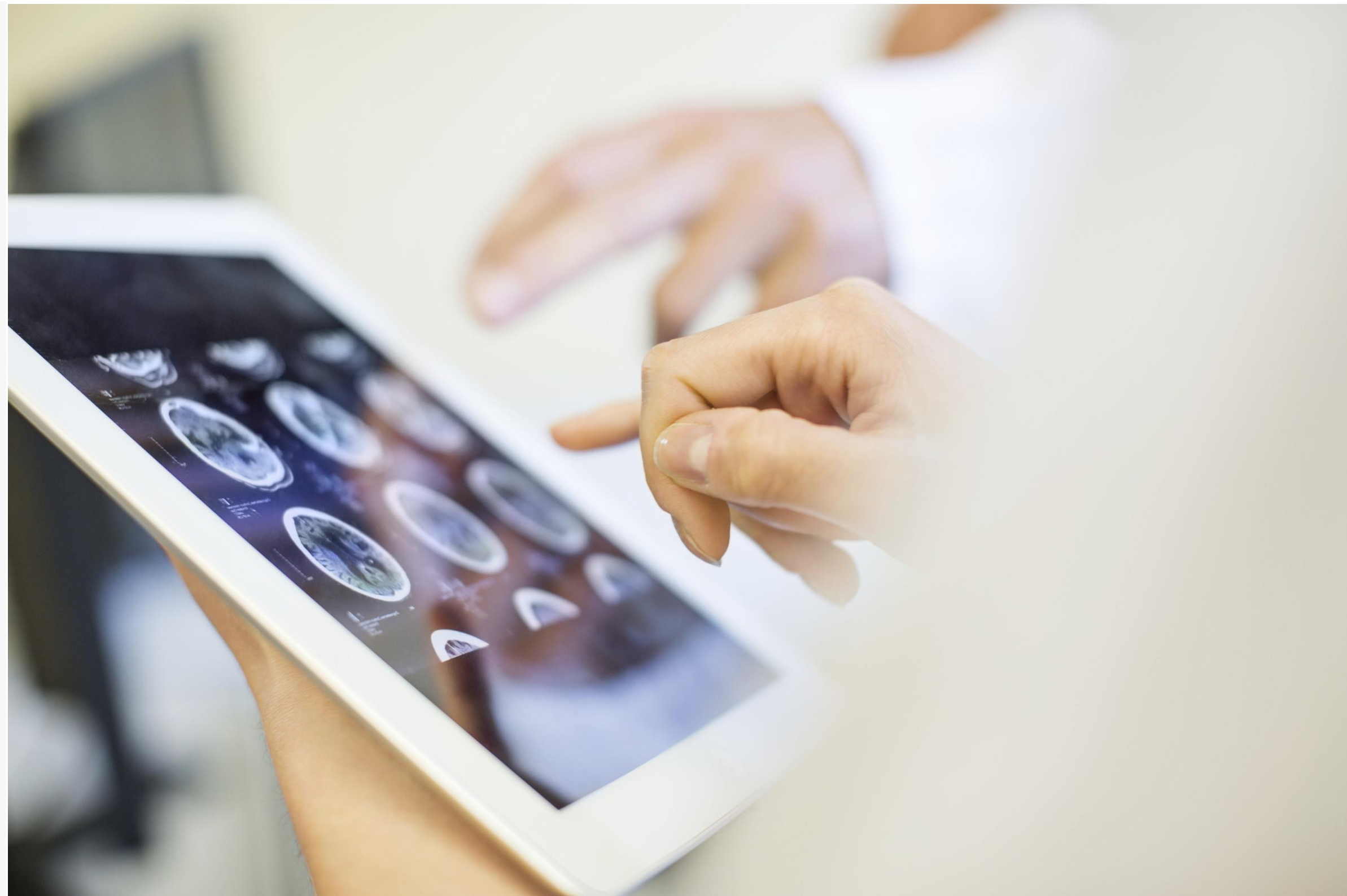
Placebo



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Clinical Trials Coverage

- Insurance coverage often set by local regulators
- Liability Insurance vs. No Fault Insurance
- Trial Specific Policies
- Annual Policies

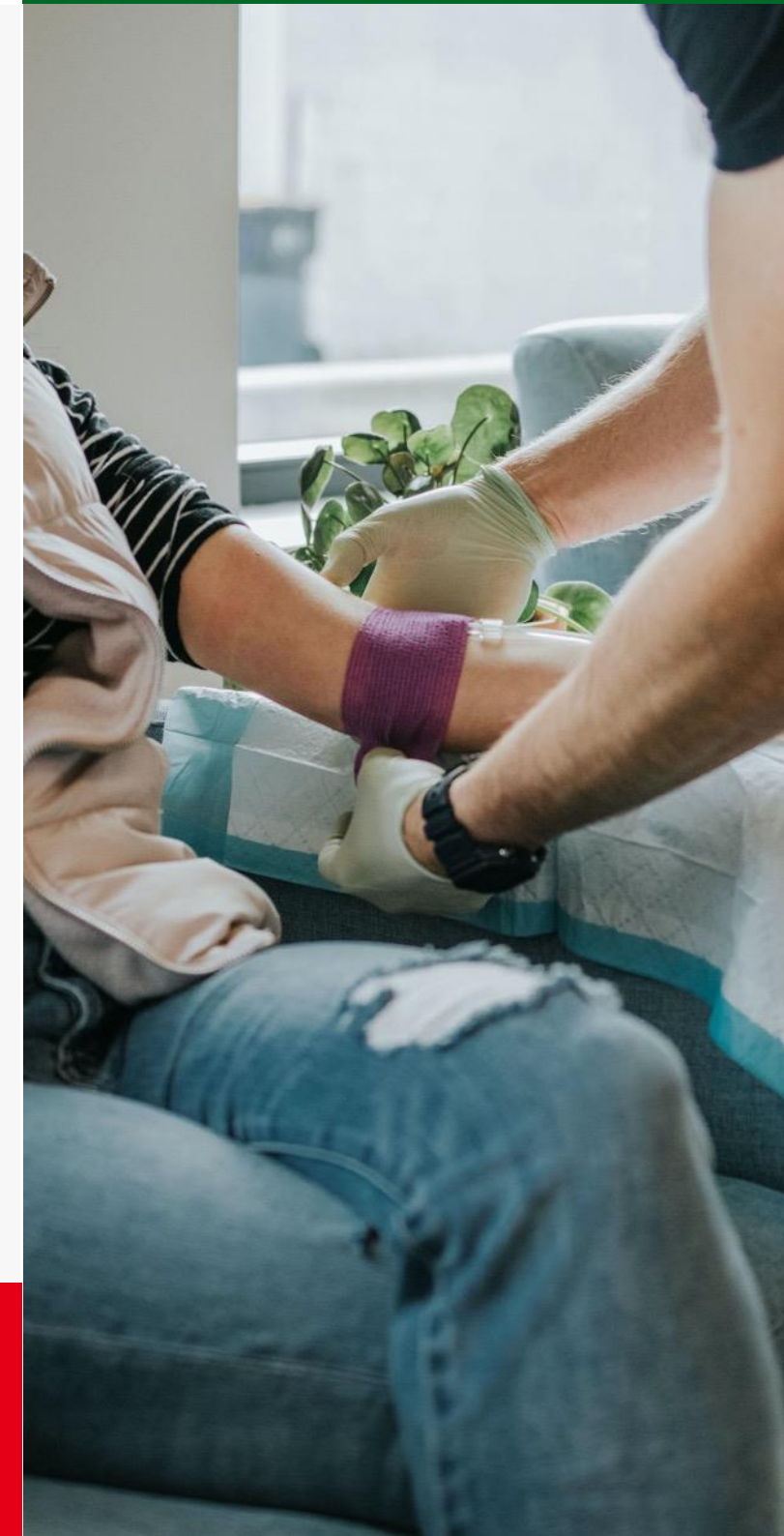




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Risk Factors

- Phase: I-IV
- Trial Type: Pharmaceutical/Medical Device/Other
- Therapeutic Area/Substance Type
- Patient Population
- Patient Number
- Territory
- Limit of Indemnity



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Pandemic Considerations

- Accelerated Timelines
- Increased news coverage and biased or fake news
- Large number of study participants
- Potential lack of critical care capacity
- Movement of trials overseas
- Human Challenge Studies

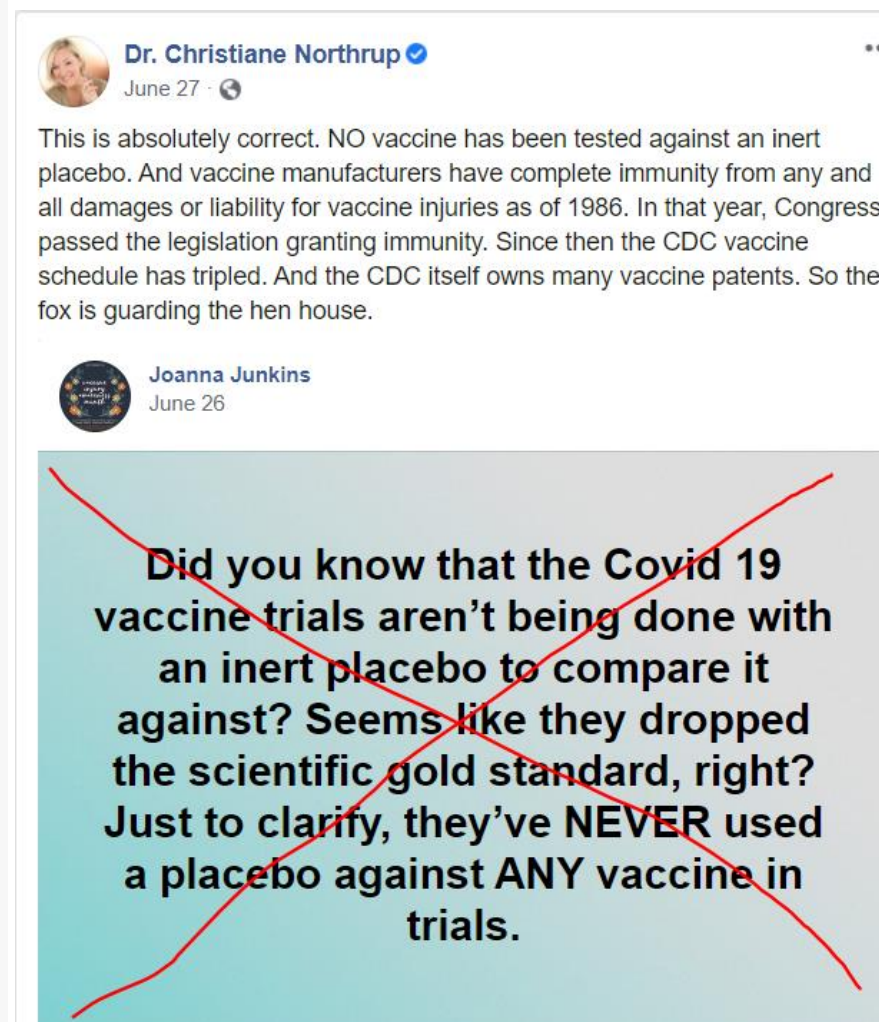
Volunteer in Oxford University's Covid-19 vaccine trial dies after 'taking placebo'

Safety fears over drug hyped to treat the coronavirus spark global confusion

UK plans COVID-19 'challenge' trials that deliberately infect volunteers

Oxford vaccine trials suspended but not 'doomed' after UK woman hit by rare neurological disorder

DOUBLE DOSE Healthy young Brits could be paid £5,000 to be reinfected with coronavirus





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COVID-19 Trial Activity

HUMAN CHALLENGE TRIALS

- Intentional exposure to the virus in a controlled setting
- Potential to provide valuable information for vaccine development.
- Ethical and Informed Consent Considerations.

GSK/MEDICAGO “GREEN” VACCINE

- Phase III Study ongoing
- Virus-Like Particle (VLP) Vaccine that utilises plants as natural bioreactors

MIXING VACCINES

- Several trials looking at the safety and efficacy of mixing different vaccines
- Important research for many low and middle-income nations

THE COVID PILL

- Of the 93 vaccine trials underway, just two are for oral tablets and seven are for nasal sprays





Contacts

Tom Daniels

Life Science Manager

Email: tom.daniels@hdi.global

Phone: +44 (0)20 7696 2724

Mobile: +44 (0) 7814 402780

Tanya Patel

Life Science Practice Underwriter

Email: tanya.patel@hdi.global

Phone: +44 (0)20 7696 2818

Mobile: +44 (0) 7814 402952

