FREE E-BOOK

25

MUST-KNOW CLINICAL TERMS

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INDEX TERMS

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MUST-KNOW CLINICAL TERMS

01

CEIC

CLINICAL INVESTIGATIONS ETHICS COMMITTEE (EUROPE)

A committee of physicians, statisticians, researchers, community advocates and others that ensures that a clinical trial is ethical and that the rights of study participants are protected. All clinical trials must be approved by a CIEC before they begin. Every institution that conducts or supports biomedical or behavioral research involving human participants must, by federal regulation, have a CIEC that initially approves and periodically reviews the research in order to protect the rights of human participants.

SYNONYMS:

CREC (Clinical Research Ethics Committee) (USA)
IRB (Institutional Review Board) (USA)
ERC (Ethical Review Committee) (UK)
REB (Research Ethics Board) (Canada)
HREC (Human Research Ethics Committee) (Australia)

NOTE

Different names for the equivalent Organizations.

CEIC TRANSLATIONS

FR CPP (Comité de protection des personnes)

ES CEIC (Comité Ético de Investigación Clínica)

Aunque el Ministerio de Sanidad lo traduce como Comité Ético de Investigación Clínica (CEIC), su traducción correcta debería ser "Comité de ética" o "Comisión de ética". En español un comité ético es aquél que actúa éticamente, mientras que un comité de ética es un comité que se ocupa de asuntos éticos. Suelen distinguirse tres tipos de comités de ética: "Comité de ética asistencial", "Comité de ética de investigación con animales" y "Comité de ética de investigación clínica" (CEIC). En los textos médicos, el más frecuente es este último, que se ocupa de los aspectos éticos de los ensayos clínicos

IT CEC (Comitato etico indipendente)

SK EK (Etická komisia)

CZ EK (Etická komise)

Institucionální hodnotící komise (IRB) nemá v ČR analogii, podle kontextu je možné ponechat aglický originál, nebo přeložit jako Etická komise.

PT CEIC (Comissão de Ética para a Investigação Clínica)

02

RANDOMIZATION

(US)

A method based on chance by which study participants are assigned to a treatment group that minimizes the differences among groups.

SYNONYMS:

Randomisation (UK)

RANDOMIZATION
TRANSLATIONS

FR

Randomisation

Répartition aléatoire

ES

Aleatorización

Distribución aleatoria (al azar)

Asignación aleatoria (al azar)

El término “randomización” puede suscitar rechazo por considerarse anglicismo innecesario.

IT

Randomizzazione

SK

Randomizácia

CZ

Randomizace

V textu studie či vědeckém článku se nejčastěji používá tento jednoznačný odborný termín. V textech určených pro laickou veřejnost, např. dopisy pacientům, je vhodnější zovlit český opis - např. náhodné rozdělení.

PT

Aleatorização

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03 SCREENING

A protocol designed to assess or examine methods of identifying a condition (or risk factors for a condition) in people who are not yet known to have the condition (or risk factor) to determine whether they will be included in the trial or excluded from the trial based on inclusion/exclusion criteria.

SCREENING
TRANSLATIONS

FR

Déspistage

Sélection

ES

Detección sistemática

Cribado

La comunidad traductora recomienda evitar el anglicismo “screening” (y también el galicismo “despistaje” admitido por la RAE en el año 2001. Puede traducirse por “detección sistemática”, “examen colectivo” o “identificación sistemática”. En muchas ocasiones es muy útil su traducción por “cribado” (que transmite claramente la idea de separación).

IT

Screening

SK

Skríning

CZ

Screening

Rovněž jako adjektivum, např. screeningová návštěva. V textech pro laickou veřejnost vhodnější opsat

PT

Rastreio

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04

ENROLLMENT

(US)

It is the act of admitting a subject for participation in a clinical trial. Enrolled subjects are said to meet formal inclusion and exclusion criteria and are scheduled to participate in a trial.

SYNONYMS:

Enrolment (UK)

NOTE

It is often used interchangeably with "inclusion"; however, inclusion means that the criteria in a protocol have been met by prospective subjects to be eligible for participation in a study.

ENROLLMENT
TRANSLATIONS

FR	Recrutement Inclusion
ES	Inclusión Reclutamiento
IT	Arruolamento
SK	Zaradenie Nábor
CZ	Přijetí do studie
PT	Inscrição

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05 INVESTIGATIONAL PRODUCT (IP)

A pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

SYNONYMS:

Investigational medical product
Investigational drug (ID)
Investigational new drug (IND)
Study drug

NOTE

Investigational product (IP) or Investigational medical product is the most proper term in the EC according to Directive 2001/20/EC. In the U.S., according to FDA regulations, the most proper term is Investigational drug (ID) or Investigational new drug (IND), which is also approved by the International Committee on Harmonization (ICH). In the Informed Consent Forms and Patient Information Sheet, the term Study drug is commonly used because requirements state that these forms have to be in "understandable language" for the lay person.

INVESTIGATIONAL PRODUCT TRANSLATIONS

FR	Produit expérimental Médicament à l'étude Médicament
ES	Producto en fase de investigación clínica (PEI)
IT	Farmaco sperimentale
SK	Skúšaný liek Skúšaný prípravok
CZ	Hodnocené léčivo Studijní léčivo Z jazykového hlediska je vhodnější termín „hodnocené léčivo", často se však používá také překlad „studijní léčivo".
PT	Inscrição

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06

ADVERSE EVENT (AE)

Any untoward medical occurrence in a study patient administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. It can be any unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

SYNONYMS:

Side effect

ADVERSE EVENT TRANSLATIONS

FR

Effet indésirable

Événement indésirable

Effet secondaire

ES

Acontecimiento adverso

Reacción adversa

Efecto secundario

Efecto colateral

Efecto indeseable

Efecto adverso

En español, las expresiones efecto adverso, acontecimiento adverso, reacción adversa, efecto secundario, efecto colateral y efecto indeseable suelen utilizarse de manera sinónima. Las más utilizadas suelen ser efecto secundario, efecto adverso, efecto colateral y reacción adversa. En farmacología, no obstante, puede ser conveniente distinguir claramente entre unas expresiones y otras según su sentido original.

IT

Evento avverso (AE)

SK

Nežiaduca udalosť

X adverse reaction – nežiaduca reakcia alebo nežiaduci účinok (rozdiel je veľký - pri reakcii príčinu poznáme, ale pri príhode ju len tušíme, t.j. súvislosť len predpokladáme)

CZ

Nežádoucí příhoda (AE)

Nežádoucí účinek

V klinických studiích se obvykle k popsání nezamýšlených účinků léčby užívá termín Nežádoucí příhoda.V příbalových informacích a materiálech pro pacienty (rovněž dle terminologie EMEA) se používá Nežádoucí účinek.

PT

Evento adverso

Efeito adverso

Reacção adversa

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07

OFF-LABEL

The practice of prescribing approved medications for other than their intended indica-tion, which is permitted by the FDA, EMEA or other regulating bodies.

OFF-LABEL TRANSLATIONS

FR Hors AMM

ES Uso extraoficial

Hasta que recibe la autorización de comercialización, gran parte del uso que se hace del fármaco en investigación es «extraoficial», sobre todo si se están analizando sus posibilidades en la curación de una enfermedad para la que no ha sido autorizado, como es frecuente. Una mención a un uso off-label puede ser anecdótica o poner de manifiesto una forma de actuar más o menos alejada de la ortodoxia.

IT (Farmaco) off-label

Letteralmente “fuori etichetta”

SK Pri neschválených indikáciách

CZ Off-label použití

Použití mimo schválenou indikaci

PT Sem indicação no rótulo

Utilização não indicada no rótulo

Utilização em indicações não aprovadas

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08 STUDY ENDPOINT

What a clinical trial is trying to measure or find out, meaning the goal of the trial.

SYNONYMS:

(Primary/Secondary) study outcome

NOTE

Typical endpoints include measurements of toxicity, response rate and survival.

STUDY ENDPOINT TRANSLATIONS

FR

Critère d'évaluation

Critère de jugement

Critère d'efficacité

ES

Criterio de valoración

Se recomienda evitar los anglicismos endpoint y punto final para designar, en los estudios clínicos, la variable predefinida que permite cuantificar el efecto de una intervención. Dentro de los estudios clínicos, endpoint puede usarse con otros cuatro significados menos frecuentes (pero en absoluto raros): a) valor extremo de un intervalo de valores; b) final o conclusión de un estudio clínico o de un período de observación; c) interrupción anticipada de un estudio clínico; d) pauta de interrupción de un estudio clínico.

IT

Endpoint dello studio

Qualsiasi studio clinico è programmato con un obiettivo, un esito e un "endpoint". L'obiettivo è la domanda di natura clinica cui si vuole dare una risposta. L'esito è lo specifico aspetto clinico capace di fornire la risposta. L'"endpoint" è la misura dell'esito clinico dalla quale – attraverso algoritmi statistici – si ricava la risposta.

SK

Koncový ukazovateľ

CZ

Cílový parametr

PT

Parâmetro do estudo

09 CASE REPORT FORM

A printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor for each trial subject.

CASE REPORT FORM
TRANSLATIONS

FR	Cahier d'observation
ES	Formulario de recogida de datos Cuaderno de recogida de datos (CRD)
IT	Scheda raccolta dati (CRF)
SK	Záznamový formulár účastníka klinického skúšania
CZ	Záznam subjektu hodnocení
PT	Caderno de Registo de Dados

10 BLINDING

(SINGLE-BLIND/DOUBLE-BLIND)

A procedure in which one or more parties to the trial are kept unaware of the treatment assignment(s). Single-blind usually refers to the subject(s) being unaware, and double-blind usually refers to the subject(s), investigator(s), monitor, and, in some cases, data analyst(s) being unaware of the treatment assignment(s).

SYNONYMS:

Masking

BLINDING
TRANSLATIONS

FR

Mise en aveugle (simple aveugle/double aveugle)

Masquage

Mise en insu

ES

Enmascaramiento (único/doble)

Separándose de la construcción inglesa, existen otras posibilidades: estudio con anonimato (con anonimato sencillo o con doble anonimato para single-blind y double-blind study), "estudio enmascarado (con enmascaramiento único" o "con enmascaramiento doble"), "estudio con ocultación" ("con ocultación única" o "con ocultación doble"), "estudio encubierto ("con encubrimiento único" o "con encubrimiento doble"), etc. En inglés, de hecho, es costumbre creciente el uso de masking en lugar de blinding.

IT

Mascheramento (cieco/doppio cieco)

SK

Zaslepenie (jednoduché zaslepenie/dvojité zaslepenie)

CZ

Zaslepení (jednoduše/dvojitě zaslepená studie)

PT

Ocultação (ocultação simples/dupla ocultação)

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STUDY MONITOR

Person employed by the sponsor or CRO (Contract Research Organization) who is responsible for determining that a trial is being conducted in accordance with the protocol. A monitor's duties may include, but are not limited to, helping to plan and initiate a trial, assessing the conduct of trials, and assisting in data analysis, interpretation, and extrapolation. Monitors work with the clinical research coordinator to check all data and documentation from the trial.

SYNONYMS:

Medical Monitor

STUDY MONITOR
TRANSLATIONS

FR	Moniteur d'étude Contrôleur d'étude
ES	Supervisor del estudio clínico/ensayo clínico Inspector del estudio clínico/ensayo clínico
IT	Responsabile del monitoraggio dello studio
SK	Monitor štúdie
CZ	Monitor studie
PT	Monitor do ensaio clínico

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12 PEER REVIEW

Review of a clinical trial by experts chosen by the study sponsor. These experts review the trials for scientific merit, participant safety and ethical considerations.

PEER REVIEW
TRANSLATIONS

FR

Évaluation par les pairs

Révision par les pairs

ES

Revisión externa por expertos

Recomendamos evitar tanto el anglicismo peer review como el calco “revisión por pares”, de uso habitual en el mundo de las publicaciones científicas. Puede traducirse como “revisión científica externa”, “revisión externa por especialistas” o “revisión externa por expertos”.

IT

Revisione paritaria

Valutazione tra pari

Revisione dei pari

Peer review

In italiano si può anche usare il termine inglese peer review.

SK

Vzájomné preskúmavanie

Partnerské hodnotenie

CZ

Peer review

Posouzení odborníky v oboru

PT

Revisão externa por especialistas

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COMPARATOR

(PRODUCT)

An investigational or marketed product (i.e., active control), or placebo, used as a referen-ce in a clinical trial.

COMPARATOR
TRANSLATIONS

FR	Comparateur
ES	Comparador
IT	Comparatore
SK	Referenčná vzorka
CZ	Srovnávací přípravek
PT	Comparador

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14 PLACEBO

A pharmaceutical preparation that contains no active substance and no treatment value. In blinded studies, it is generally made to look just like the active product. Experimental treatments are often compared with placebos to assess the treatment's effectiveness.

PLACEBO

TRANSLATIONS

FR	Placebo
ES	Placebo
IT	Placebo
SK	Placebo
CZ	Placebo V textech pro pacienty může být vhodnější použít opis, např. neúčinná látka.
PT	Placebo

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15 INFORMED CONSENT

A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent precedes enrolment and is documented by means of a written, signed, and dated consent form. No informed consent may include any "language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence."

INFORMED CONSENT
TRANSLATIONS

FR	Consentement éclairé
ES	Consentimiento informado
IT	Consenso informato
SK	Informovaný súhlas
CZ	Informovaný souhlas
PT	Consentimento informado

Se o declarante não estiver em condições de dar o seu consentimento por escrito, este pode ser dado oralmente na presença de duas testemunhas, de acordo com a legislação vigente.

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16 PATIENT INFORMATION SHEET

A comprehensive information sheet given to all patientsso that they can make a fully informed decision on whether to take part in a clinical trial. Information on all procedures, assessments, visits, risks, benefits, side-effects, contacts etc are included. This is an integral part of the informed consent process.

PATIENT INFORMATION SHEET

TRANSLATIONS

FR	Fiche d'informationdestinéeau patient Documentd'information auxpatients
ES	Folleto informativo para el paciente
IT	Informativa per il paziente
SK	Informácie pre pacienta
CZ	Informace pro pacienty
PT	Folha Informativa para o Doente

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17 WITHDRAWAL

The act of reducing the degree of participation by a subject in a clinical trial. Subjects may withdraw permission for Sponsor use of data derived from study participation, privacy waivers, informed consent, or withdraw from active treatment component of a clinical trial but continue to be observed.

NOTE

Full withdrawal from participation in a study is called discontinuation.

WITHDRAWAL
TRANSLATIONS

FR

Arrêt

Interruption

ES

Abandono

Retirada

El traductor tendrá muy en cuenta la diferencia entre retirar (transitivo) y retirarse. En inglés, en nuestro contexto, withdraw se refiere a todo tipo de retiradas: 1) del paciente del estudio (por voluntad propia o por obligación); 2) del consentimiento informado por parte del paciente; y 3) del tratamiento. Pero también a lo que conocemos como «abstinencia» de un fármaco (o sobre todo de una droga). La retirada del paciente del estudio antes de que acabe ocasiona un sinfín de problemas estadísticos y de infraestructura, por lo que los laboratorios toman todo tipo de precauciones ante esta opción totalmente voluntaria del participante.

IT

Ritiro

SK

Vyradenie

Odstúpenie

CZ

Částečné stažení ze studie

PT

Retirada

A retirada total da participação de um estudo é chamada de descontinuação.Ver também definição 20.

18 COMPLIANCE

Adherence to all the trial-related requirements, good clinical practice (GCP) require-ments, and the applicable regulatory requirements.

COMPLIANCE
TRANSLATIONS

FR	Conformité	
	Observance	
ES	Cumplimiento	Adhesión al tratamiento
	Observancia (del tratamiento)	Compliancia
	Adherencia al tratamiento	Cumplimiento terapéutico
	Pese a que el término compliancia es correcto, suscita rechazo por anglicismo innecesario.	
IT	Compliance	
	Conformità	
SK	Dodržiavanie pokynov	
	Konanie v súlade	
CZ	Kompliance	
	Dodržování pokynů	
PT	Cumprimento	
	Adesão	

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CLINICAL TRIAL

A systematic study of a test treatment, drug or device in one or more human subjects. An investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy.

SYNONYMS:

Study
Investigation (UK)
Research (US)

CLINICAL TRIAL
TRANSLATIONS

FR

Essai clinique

Étude clinique

Recherche clinique

ES

Ensayo clínico

Estudio clínico

Se usa con frecuencia en un sentido más restringido, referido tan solo a los estudios terapéuticos de intervención con fármacos.Suele abreviarse a “ensayo” o “estudio” en sus formas compuestas: ensayo comparativo, estudio aleatorizado, ensayo de fase II, etc.

IT

Studio clinico

Sperimentazione clinica

SK

Klinická štúdia

CZ

Klinická studie

Klinické hodnocení

PT

Ensaio clínico

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20 DISCONTINUATION

The act of concluding participation in a trial for an enrolled subject. Various types of discontinuation occur: e.g., dropout (active discontinuation by a subject), investigator-initiated, lost to follow-up (subject ceased participation without notice or action by the subject), sponsor-initiated discontinuation (cancelling the trial). Synonym: termination (now considered non-standard).

SYNONYMS:

Dropout
Termination

NOTE

Termination is now considered non-standard

DISCONTINUATION
TRANSLATIONS

FR

Arrêt

Suspension

Interruption

Abandon

Sortie de l'étude

ES

Interrupción

Dejar de (administrar o de recibir)

IT

Interruzione

Sospensione anticipata

SK

Predčasné ukončenie účasti

CZ

Předčasné ukončení účasti na studii

Nutno rozlišovat od řádného ukončení studie, tj. absolvování všech návštěv včetně koncové návštěvy, procedur atd.

PT

Descontinuação

Desistência

Abandono

Podem existir vários tipos de descontinuação: desistência (descontinuação activa por um participante), por iniciativa do investigador, perda de acompanhamento (o paciente abandonou a participação sem avisar), por iniciativa do promotor (cancelamento do ensaio).

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PROTOCOL

A document that describes the objective(s), design, methodology, statistical considera-tions, and organization of a trial. It also gives a detailed plan of treatment including the dose and schedule of any drugs used. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced docu-ments. Also used as a synonym for “Clinical Trial”.

PROTOCOL
TRANSLATIONS

FR	Protocole
ES	Protocolo
IT	Protocollo
SK	Protokol
CZ	Protokol
PT	Protocolo

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CLINICAL TERMS

22 BASELINE

Information gathered at the beginning of a study from which variations found in the study are measured.

BASELINE TRANSLATIONS

FR	Étude ouverte Étude en ouvert
ES	Estudio/Ensayo abierto
IT	Studio in aperto
SK	Otvorená štúdia
CZ	Otevřená studie
PT	Estudo cruzado

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23 PARALLEL STUDY

A Parallel study is a type of clinical study where two groups of treatments, A and B, are given so that one group receives only A while another group receives only B.

PARALLEL STUDY
TRANSLATIONS

FR	Étude parallèle
ES	Ensayo paralelo Estudio/Ensayo con grupos paralelos En ocasiones puede darse el uso de “estudio en paralelo”.
IT	Studio parallelo
SK	Štúdia s paralelnými skupinami
CZ	Studie s paralelními skupinami
PT	Estudo paralelo

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24 CROSS-OVER STUDY

A crossover study is where at first one group receives treatment A and later followed by treatment B while the other group receives treatment B followed by treatment A

CROSS-OVER STUDY
TRANSLATIONS

FR	Étude croisée
ES	Estudio/Ensayo cruzado Estudio/Ensayo con grupos cruzados
IT	Studio in cross-over
SK	Skrížená štúdia
CZ	Cross-over studie Zkřížená studie
PT	Estudo cruzado

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25 OPEN-LABEL STUDY

An open-label trial or open trial is a type of clinical trial in which both the researchers and participants know which treatment is being administered.[1] [2] This contrasts with single blind and double blind experimental designs, where participants are not aware of what treatment they are receiving (researchers are also unaware in a double blind trial)

OPEN-LABEL STUDY
TRANSLATIONS

FR	Étude ouverte Étude en ouvert
ES	Estudio/Ensayo abierto
IT	Studio in aperto
SK	Otvorená štúdia
CZ	Otevřená studie
PT	Estudo cruzado

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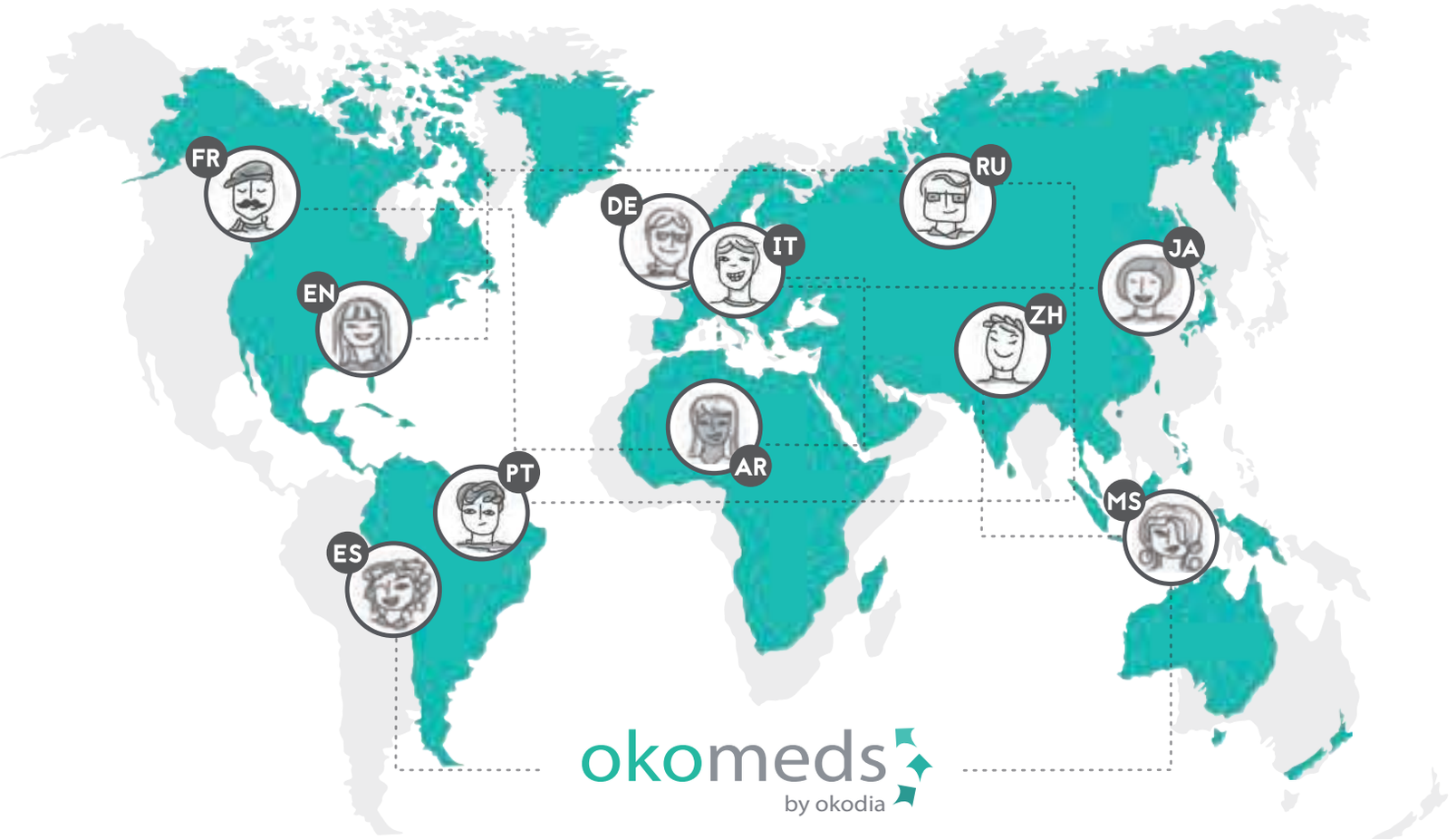
GLOBAL TRANSLATIONS



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Uri Weinberg, Novocure

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