Country	Branding/Logo Requirements	Photo Inclusion Requirements	Study Medication Name Requirements
Argentina	N/A	N/A	"medicacion del estudio"
Australia	reading level should be equal to reading level of ICF.	N/A	study drug or investigational medicine.
Austria	N/A	N/A	In clinical trials ‘Klinische Prüfung’ Study Drug or Prüfpreparat or sometimes Studienmedikament
Belgium	logos on retention materials (ex. Water bottles) not allowed. Direct advertisements to the public is not allowed (for example social media ads cannot directly mention study name and sponsor when they pop-up)	N/A	studiegeneesmiddel or trial drug
Brazil	do not use logos in recruitment materials	N/A	study drug already adapted locally to "medicação do estudo"

Canada	Sponsor logos or legal identity within any recruitment materials can stay. The name of the Janssen investigational drug or any J&J drug name cannot be mentioned, including the compound number embedded in the protocol number which may appear in the body or footer of the above documents (e.g. you can use DIA4004 but not the full code 28431754DIA4004.)	Remove pictures of actual people smiling and all happy, they give the wrong impression.	Investigational drug or investigational study medication. Do not use the generic name of any J&J drug. Only use the generic name for non-J&J drugs.
China	Reserve the version number and version date for any docs	N/A	study drug or investigational medicine
Czech Republic	N/A	N/A	"zkoušený lék / zkoušené léky" or hodnocené léčivo
Denmark	N/A	N/A	forsøgslægemiddel
France	avoid over -representation "Janssen Research & Development, LLC > Janssen"	N/A	Trade name of study medication cannot be mentioned.
Germany	no company logo, no full study number, only acronyms allowed . No link to study or company on recruitment materials pre ICF signature	N/A	Prüfmedikament = investigational study drug or compound name.
Greece	No sponsor logos	N/A	N/A

Hungary	In any patient-facing document to be delivered before the patient signs the consent form – the Sponsor logo and name, study name, protocol number etc should not be present. Only the indication.	N/A	investigational medicine
India	N/A	N/A	Investigational medicine - For Clinical Trial use only
Israel	N//A	N/A	study medication
Italy	N/A	N/A	N/A
Japan	N/A	N/A	N/A
Malaysia	N/A	N/A	N/A
Mexico	N/A	Photos must be approved by Central team and then approval by local EC/IRB/MoH.	Study medication or investigational medicine

Netherlands	logo on retention materials (ex. water bottles) are not allowed. Direct advertisements to the public is not allowed (for example social media ads cannot directly mention study name and sponsor when they pop-up) Please also check what the requirements are for an EU CTR submission	N/A	study drug or onderzoeksmiddel
New Zealand	N/A	N/A	Study Drug
Poland	N/A	N/A	N/A

Republic of Korea (South Korea)	N/A	N/A	임상시험용 의약품 (study medication)
South Africa	N/A	N/A	N/A
Spain	No logo restrictions, avoid advertizing data in patient materials	N/A	study medication = "medicación del estudio".
Sweden	All IPE material have to be clearly versioned; ie each new version should have a new version number and a version date that is available in the footer of the document.	N/A	studieläkemedel

Taiwan	N/A	N/A	N/A
Turkey	No QR codes allowed	N/A	"çalışma ilacı"for study drug.
United Kingdom	use the standard Janssen Branding templates, or templates provided by the study team.	N/A	study drug
United States	N/A	N/A	Study Medication or Investigational medicine.

How are patients referred to?	Language and Tone Requirements
patient/ participant	No coercive language (e.g., safety or efficacy claims, etc.) Language used is as non-technical as practical and written to be understandable to the patient/participant. For adolescents, use VOS, not USTED
participants	no promotional tone of the language, in lay terms
participant	N/A
deelnemer (participant or patient) Do Not use subject	No promotional tone. Keep to facts.
participant	No phrases that claim an investigational drug is effective/safe and cannot be promotional in tone information must be clear and easily accessed by the participant.

participant	Cannot use words or phrases the claim an investigational drug is effective/safe and cannot be promotional in tone. i.e. 'treatment', 'advanced therapy', 'successful in other trials'
participant	don't drug claim as effective/safe
participant = účastník patient = pacient avoid subject or účastník klinického hodnocení	cannot encourage subjects to take part in study, everything needs to be voluntary
"Försökperson"- subject	Cannot be promotional in tone
patient name should be "a participant".	No promotional in tone, don't mention the study medication is safe or effective
participant	no promotional tone additionally the word: race
N/A	N/A

subject/participant	The recruitment call must not be promotional, nor contain the trade name of the investigational medicinal product, the manufacturer or the identity of the person authorized to place it on the market.

Subject/ Participant	N/A
participant	Cannot be promotional in tone

N/A	Cannot be promotional in tone
Subject	can't use the words effective/safe for investigational drug
participant	language includes inducement element, e.g., 'you can access to free treatment upon joining clinical trial'. LGBT is prohibited in MYS, language pertaining to LGBT should be cautious.
Participant or subject	Avoid phrases that claim an investigational drug is effective/safe and cannot be promotional in tone. Use simple language and use words that are common

deelnemer (participant)	no promotional tone, keep to facts
Participant	Need to be in lay terms. Less scientific and medical terminology.
participant	no promotional in tone, consequency in using Pan/Pani or Pan(i)

임상시험 대상자 (study subject)	Use the most conservative tone
N/A	N/A
Sujeto or paciente	Promotional tone cannot be used.
forskningsperson or försoeksperson	N/A

N/A	N/A
"katılımcı" for participant or "Gönüllü" for subject/participant/partner.	cannot be promotional in tone, cannot promote safety/efficacy
subject or participant and align with language and terms used in the ICF.	Use conversation style instead of a passive voice and to use "we" etc. also language cannot be seen to coerce or advertise, information needs to be accurate, fair and balanced
participant	Cannot be promotional in tone

Local Authorities Required Phrases	Languages Required for Translation	EORI#s for EU-CTR
N/A	N/A	N/A
N/A	Australian English	N/A
specific statements required for ICF only	N/A	ATEOS1000008515
N/A	Belgium (French, Dutch, German)	BE0403834160
N/A	Portuguese	N/A

In Canada we need English and French CDN. English CDN is not always necessary but if translated to CND English from USA English, a COT is required.	Canada (English, French)	N/A
N/A	Simplified Chinese	N/A
EU CT n. needs to be on every subject´s documents (e.g. informed consent, wallet card, diaries, etc.)	N/A	N/A
N/A	N/A	N/A
N/A	French	FR562 033 068 00 130
N/A	N/A	DE2226251
N/A	N/A	GR099325655

As per CEC requirement for Hungary all patient recruitment materials must include a statement referring to the approval of the study. Without this the document will be rejected. A vizsgálatot az Egészségügyi Tudományos Tanács Klinikai Farmakológiai Etikai Bizottságának (ETT-KFEB) támogató véleménye alapján a Nemzeti Népegészségügyi és Gyógyszerészeti Központ (NNGYK) hagyta jóvá.	N/A	HU0000497185
N/A	India (English, Hindi, Gujarati, Marathi, Bengali, Tamil, Telugu, Kannada, Punjabi)	N/A
N/A	Israel (Hebrew, Arabic)	N/A
N/A	N/A	IT02707070963
N/A	N/A	N/A
N/A	MYS (English), MY (Simplified Chinese), MYS (Malay)	N/A
Just to indicate name of document_language_version #_date in the footer of each document	Spanish (Mexico)	N/A

N/A	Dutch	BE0403834160
N/A	N/A	N/A
N/A	N/A	PL 5222665719 00000

Followings are to be included in patient recruitment materials; 1. Name of clinical trial: All titles approved by the Ministry of Food and Drug Safety or IRB ex. In this 77242113UCO2001 study, we will use 중등증에서 중증의 활성 궤양성 대장염의 치료에서 JNJ-77242113의 유효성 및 안전성을 평가하기 위한 제2b상, 다기관, 무작위 배정, 위약 대조, 용량 범위 설정 임상시험 2.Purpose: Brief reasons for conducting clinical trials, such as effectiveness 3. Clinical trial method: group information, randomization, visit schedule, participation period, test type 4.Eligibility and include criteria: can be determined by Sponsor 5.Name (corporation name), address, and contact information of the sponsor and the Principal investigator: the name, address, and contact information of the sponsor and the name, address, and contact information of the Principal investigator of the conducting institution - Please make a blank to insert those information	N/A	N/A
N/A	N/A	N/A
N/A	N/A	ES-A-28925899.
N/A	N/A	SE5560240037

Mandatory wording per local regulatory to be added in all advertisement (recruitment material). "This advertisement has been reviewed and approved by IRB/EC, and the content of the reprint (repost) shall not be modified. "**經人體試驗委員會/倫理審**查委員會審查核准，**且轉載(貼)不得修改**內容	N/A	N/A
N/A	N/A	N/A
N/A	English (US, UK)	GB207929448000 IRAS: 1006875
N/A	English, US Spanish.	N/A

Other Requirements	Questions for LTMs
N/A	
N/A	
N/A	
N/A	
Any product/material that the study has the intention to provide to the participant need to have a use justification. Remove contact to USA	

Images: Remove images of people and image disclaimers about models Footer: Requires updates to remove protocol reference.	
	N/A
N/A	
N/A	
1) No mention of reimbursement is allowed for any study 2) No mention to "race" as it can be considered as too seducer. 3) It is prohibited to mention any terms allowing indirect identification of a product (single route of administration, dosage, specific biological monitoring, therapeutic class or unique mechanism of action in the	
	information distributed regarding medicinal products/IP/substances, needs to be in compliance with German drug advertising law (Heilmittelwerbegesetz)
N/A	

N/A	Inquire if reimbursement is required
FOR ANY CLINICAL TRIAL - CTRI (Clinical Trials Registry- India) REGISTRATION IS MANDATORY FOR INDIA	
Please keep brochures to open from right to left if written in Hebrew or Arabic	
recruitment material must not report IMP name but only protocol name	
N/A	

N/A

N/A

N/A

N/A

Only travel costs are reimbursed

N/A

As per South Africa's Pharma Ethics guidelines: "We require that there must be no references to costs of participation and reimbursement for study related activities in recruitment materials".

N/A

N/A

N/A

Cannot have encouraging wording (congrats, congratulations, thank you). Remove these sentences.

information should be produced locally using local language and information relevant to participants in that country

N/A

Response from LTMs