PROTOCOL INFORMATION ON A CLINICAL TRIAL ON A MEDICINAL PRODUCT FOR HUMAN USE CONDUCTED IN A THIRD COUNTRY (i.e. a country outside of the EEA)

Note: To ensure consistency the numbering of this form is based on the Clinical Trial Application form of the EU.

A. TRIAL IDENTIFICATION

A.2	EudraCT number	**2014-002258-38**
A.3	Full title of the trial:	
	English	**The effect of vitamin D supplement in subjects with type 2 diabetes mellitus**
A.3.1	Title of the trial for lay people, in easily understood, i.e. non-technical, language:	
	English	**The effect of vitamin D in subjects with diabetes mellitus**
A.3.2	Name or abbreviated title of the trial where available:	
	English	**Vitamin D and diabetes mellitus**
A.4.1	Sponsor's protocol code number:	**20062011**
A.5	Additional international study identifiers	
A.5.1	ISRCTN number[1]:	
A.5.2	US NCT number[2]:	
A.5.3	WHO Universal Trial Number (UTN):	
A.5.4	Other Identifier:	
A.7	Is the trial part of an agreed Paediatric Investigation Plan?	**No •**
A.8	EMA Decision number of Paediatric Investigation Plan:	

B. IDENTIFICATION OF THE SPONSOR OF THE TRIAL

B.1	**SPONSOR**
B.1.1	Name of organisation:
B.1.3.4	Country

B.3	**STATUS OF THE SPONSOR:**	
B.3.1	Commercial:	**?**
B.3.2	Non commercial:	**?**

B.4	**Source(s) of Monetary or Material Support for the clinical trial (repeat as necessary):**
B.4.1	**Name of organisation:**
B.4.2	**Country:**

B.5	**Contact point[3] designated by the sponsor for further information on the trial**
B.5.1	Name of organisation:
B.5.2	Functional name of contact point (e.g. "Clinical Trial Information Desk"):
B.5.3	Address:
B.5.3.1	Street address
B.5.3.2	Town/city
B.5.3.3	Post code
B.5.3.4	Country
B.5.4	Telephone number:
B.5.5	Fax number:
B.5.6	E-mail: (use a functional e-mail address rather than a personal one)

C. THIRD COUNTRY DATA PROVIDER IDENTIFICATION

C.1.5.1	Do you want a copy of this CT Information form data saved on EudraCT as an XML file?	**No** ●
C.1.5.1.1	If 'Yes', provide the e-mail address(es) to which it should be sent (up to 5 addresses):	
C.1.5.1.2	Do you want to receive this via password protected link(s)?	**No** ●

If you answer No to question C.1.5.1.2 the XML file will be transmitted by less secure e-mail link(s)

D. INFORMATION ON EACH IMP

Information on each 'bulk product' before trial-specific operations (blinding, trial specific packaging and labelling) should be provided in this section for each investigational medicinal product (IMP) being tested including each comparator and each placebo, if applicable. **For placebo go directly to D8.**

D.1	**IMP IDENTIFICATION**	
Indicate which of the following is described below, then repeat as necessary for each of the numbered IMPs to be used in the trial:		
D.1.1	This refers to the IMP number:	**PR1**
D.1.2	IMP being tested	**Yes •**
D.1.3	IMP used as a comparator	**No •**

D.2	**STATUS OF THE IMP.**	
D.2.1	Has the IMP to be used in the trial a marketing authorisation?	**No •**
If the IMP has a marketing authorisation but the trade name and marketing authorisation holder are not fixed in the protocol, go to section D.2.2.		
D.2.1.1	If 'Yes', specify for the product to be used in the clinical trial:	
D.2.1.1.1	Trade name **Vi- De 3**	
D.2.1.1.1.1	EV Product Code (where applicable)	
D.2.1.1.2	Name of the Marketing Authorisation Holder:	**Novartis Pharma AG**
D.2.1.2	Country that granted the Marketing Authorisation	**Switzerland**

D.2.2	Situations where an IMP to be used in the CT has a Marketing Authorisation in the country concerned, but the protocol allows that any brand of the IMP with a Marketing Authorisation in that country be administered to the trial subjects and it is not possible to identify the IMP(s) in advance of the trial start	
D.2.2.1	In the protocol, is treatment defined only by active substance?	**No •**
D.2.2.1.1	If 'Yes', give active substance in D.3.8 or D.3.9	
D.2.2.2	In the protocol, do treatment regimens allow different combinations of marketed products used according to local clinical practice at some or all investigator sites in the trial?	**No •**
D.2.2.2.1	If 'Yes', give active substance in D.3.8 or D.3.9	
D.2.2.3	The products to be administered as IMPs are defined as belonging to an ATC group[4]	**No •**
D.2.2.4	Other:	**Yes •**
D.2.2.4.1	If 'Yes', please specify **Cholecalciferol**	

D.2.5	Has the IMP been designated in this indication as an orphan drug in the Community?	**No •**
D.2.5.1	If 'Yes', give the orphan drug designation number[5]	

D.3	**DESCRIPTION OF THE IMP**	
D.3.1	Product name where applicable	**vi- De 3**
D.3.2	Product code where applicable[6]	**UN5/920424/0**
D.3.4	Pharmaceutical form (use standard terms):	**Oral drops, solution**
D.3.4.1	Is this a specific paediatric formulation?	**No •**
D.3.7	Routes of administration (use standard terms):	**Oral use**

D.3.8	Name of each active substance (INN or proposed INN if available):

D.3.9	Other available name for each active substance (provide all available):	
D.3.9.1	CAS[7] number	
D.3.9.2	Current sponsor code	
D.3.9.3	Other descriptive name	
D.3.9.4	EV Substance code	
D.3.10	Strength (specify all strengths to be used):	
D.3.10.1	Concentration unit:	
D.3.10.2	Concentration type ("exact number", "range", "more than" or "up to"):	
D.3.10.3	Concentration (number):	

D.3.11	Type of IMP	
	Does the IMP contain an active substance:	
D.3.11.1	Of chemical origin?	**Yes •**
D.3.11.2	Of biological / biotechnological origin (other than Advanced Therapy IMP (ATIMP)?	**No •**
Is this a:		
D.3.11.3	Advanced Therapy IMP (ATIMP)?	**No •**
D.3.11.3.1	Somatic cell therapy medicinal product?	**No •**
D.3.11.3.2	Gene therapy medicinal product?	**No •**
D.3.11.3.3	Tissue Engineered Product?	**No •**
D.3.11.3.4	Combination ATIMP (i.e. one involving a medical device)?	**No •**
D.3.11.3.5	Has the Committee on Advanced Therapies issued a classification for this product?	**No •**
D.3.11.3.5.1	If 'Yes' please provide that classification and its reference number:	
D.3.11.4	Combination product that includes a device, but does not involve an Advanced Therapy?	**No •**
D.3.11.5	Radiopharmaceutical medicinal product?	**No •**
D.3.11.6	Immunological medicinal product (such as vaccine, allergen, immune serum)?	**No •**
D.3.11.7	Plasma derived medicinal product?	**No •**
D.3.11.8	Extractive medicinal product?	**No •**
D.3.11.9	Recombinant medicinal product?	**No •**
D.3.11.10	Medicinal product containing genetically modified organisms?	**No •**
D.3.11.11	Herbal medicinal product?	**No •**
D.3.11.12	Homeopathic medicinal product?	**No •**
D.3.11.13	Another type of medicinal product?	**Yes •**
D.3.11.13.1	If 'another type of medicinal product' specify the type of medicinal product	
	Cholecalciferol	
D.3.12	Mode of action (free text[8])	
	Increase calcium absorption from bone, allow calcium reabsorption from kidney	

D.8 INFORMATION ON PLACEBO (if relevant; repeat as necessary)		
D.8.1	Is there a placebo?	**No •**

D.8.2	This refers to placebo number:
D.8.3	Pharmaceutical form
D.8.4	Route of administration

E. GENERAL INFORMATION ON THE TRIAL

This section should be used to provide information about the aims, scope and design of the trial. When the protocol includes a sub-study in the country concerned section E.2.3 should be completed providing information about the sub-study. To identify it check the sub-study box in the 'Objective of the trial' question below.

E.1	**MEDICAL CONDITION OR DISEASE UNDER INVESTIGATION**
E.1.1	Specify the medical condition(s) to be investigated[9] (free text): **English** **Type 2 diabetes mellitus**
E.1.1.1	Medical condition in easily understood language **English** **Diabetes mellitus**
E.1.1.2	Therapeutic area **Body processes [G] - Metabolic Phenomena [G03]**
E.1.2	MedDRA version, system organ class, level, term and classification code[10]: Version System Organ Class Classification Code Term Level
E.1.3	Is any of the conditions being studied a rare disease[11]? **No •**

E.2	**OBJECTIVE OF THE TRIAL**
E.2.1	Main objective **English** **The effect of vitamin D in type2 diabetes mellitus as regards glycemic control and lipid profile**
E.2.2	Secondary objectives **English** **Not applicable**
E.2.3	Is there a sub-study? **No •**
E.2.3.1	If 'Yes' give the full title, date and version of each sub-study and their related objectives

E.3	**PRINCIPAL INCLUSION CRITERIA (list the most important)**
	English **Adult subjects with type 2 diabetes mellitus**

E.4	**PRINCIPAL EXCLUSION CRITERIA (list the most important)**
	English **subjects with hepatic, renal malignancy, bone disease, gall bladder disease, and gastrointestinal disease, history of anticonvulsants, calcium, or vitamin D intake for the last 3 months.**

E.5	**END POINT(S)**
E.5.1	Primary End Point (repeat as necessary)[12] **English** **After completing intake of 4500 IU of vitamin D tablets.**
E.5.1.1	Timepoint(s) of evaluation of this end point **English** **Two months.**
E.5.2	Secondary End Point (repeat as necessary) **English** **When FBS, HbA1c, 25- hydroxy vitamin D, lipid profile will be measured to all subjects after completing the vitamin D supplement**
E.5.2.1	Timepoint(s) of evaluation of this end point **English** **Three months**

E.6	**SCOPE OF THE TRIAL** – Tick all boxes where applicable	
E.6.1	Diagnosis	**No •**
E.6.2	Prophylaxis	**No •**
E.6.3	Therapy	**Yes •**
E.6.4	Safety	**No •**
E.6.5	Efficacy	**No •**
E.6.6	Pharmacokinetic	**No •**
E.6.7	Pharmacodynamic	**No •**
E.6.8	Bioequivalence	**No •**
E.6.9	Dose Response	**No •**
E.6.10	Pharmacogenetic	**No •**
E.6.11	Pharmacogenomic	**No •**
E.6.12	Pharmacoeconomic	**No •**
E.6.13	Others	**No •**
E.6.13.1	If others, specify scope of the trial:	

E.7	**TRIAL TYPE AND PHASE[13]**	
E.7.1	Human pharmacology (Phase I)	**No •**
Is it:		
E.7.1.1	First administration to humans	**No •**
E.7.1.2	Bioequivalence study	**No •**
E.7.1.3	Other	**No •**
E.7.1.3.1	If other, please specify	
E.7.2	Therapeutic exploratory (Phase II)	**No •**
E.7.3	Therapeutic confirmatory (Phase III)	**No •**
E.7.4	Therapeutic use(Phase IV)	**Yes •**

E.8	**DESIGN OF THE TRIAL**	
E.8.1	Controlled	**No •**
	If 'Yes', specify:	
E.8.1.1	Randomised:	**Yes •**
E.8.1.2	Open:	**Yes •**
E.8.1.3	Single blind:	**No •**
E.8.1.4	Double blind:	**No •**
E.8.1.5	Parallel group:	**No •**
E.8.1.6	Cross over:	**No •**
E.8.1.7	Other:	**No •**
E.8.1.7.1	If 'Yes' to other specify:	
E.8.2	If controlled, specify the comparator:	
E.8.2.1	Other medicinal product(s)	**No •**
E.8.2.2	Placebo	**No •**
E.8.2.3	Other	**No •**
E.8.2.3.1	If other, please specify :	
E.8.2.4	Number of treatment arms in the trial	
E.8.3	Will this trial be conducted at a single site globally?	**Yes •**
E.8.4	Will this trial be conducted at multiple sites globally?	**No •**
E.8.6.2	Trial being conducted completely outside of the EEA:	**No •**
E.8.6.3	Specify the countries outside of the EEA in which trial sites are planned: **Egypt**	
E.8.6.4	Number of sites anticipated world-wide:	**1**
E.8.7	Trial having an independent data monitoring committee:	**Yes •**
E.8.8	Definition of the end of trial: If it is the last visit of the last subject, please enter "LVLS". If it is not LVLS provide the definition and justification: **English** **When the last subject completed its vitamin d supplement for two months and the laboratory data will be measured.**	
E.8.9	Initial estimate of the duration of the trial[14] (years, months and days):	
E.8.9.2	In all countries concerned by the trial (years, months and days)	years **9** months days

E.8.10	Proposed date of start of recruitment	
E.8.10.2	In any country	**2014-03-01**

F. POPULATION OF TRIAL SUBJECTS

F.1	AGE RANGE		
F.1.1	Less than 18 years?		**No •**
	If 'Yes' specify the estimated number of subjects planned in each age range for the whole trial:		
		Approx. No. of patients[15]	
F.1.1.1	In utero	()	**No •**
F.1.1.2	Preterm newborn infants (up to gestational age < 37 weeks)	()	**No •**
F.1.1.3	Newborns (0-27 days)	()	**No •**
F.1.1.4	Infants and toddlers (28 days - 23 months)	()	**No •**
F.1.1.5	Children (2-11 years)	()	**No •**
F.1.1.6	Adolescents (12-17 years)	()	**No •**
F.1.2	Adults (18-64 years)	(**100**)	**Yes •**
F.1.3	Elderly (>= 65 years)	()	**No •**

F.2	GENDER	
F.2.1	Female	**Yes •**
F.2.2	Male	**Yes •**

F.3	GROUP OF TRIAL SUBJECTS	
F.3.1	Healthy volunteers	**No •**
F.3.2	Patients	**Yes •**
F.3.3	Specific vulnerable populations	**No •**
F.3.3.1	Women of child bearing potential not using contraception	**No •**
F.3.3.2	Women of child bearing potential using contraception	**No •**
F.3.3.3	Pregnant women	**No •**
F.3.3.4	Nursing women	**No •**
F.3.3.5	Emergency situation	**No •**
F.3.3.6	Subjects incapable of giving consent personally	**No •**
F.3.3.6.1	If 'Yes', specify:	
F.3.3.7	Others:	**No •**
F.3.3.7.1	If others, specify the specific vulnerable populations	

F.4	PLANNED NUMBER OF SUBJECTS TO BE INCLUDED:	
F.4.2.2	In the whole clinical trial	**100**

F.5 **PLANS FOR TREATMENT OR CARE please specify** (free text):

English **None**

G. CLINICAL TRIAL SITES INFORMATION

G.4	NETWORKS TO BE INVOLVED IN THE TRIAL (e.g. Paediatric Networks involved in the trial)
G.4.1 G.4.3.4	Name of Organisation: Country

H.4 THIRD COUNTRY IN WHICH THE TRIAL WAS FIRST AUTHORISED

H.4.1	Clinical trial has been reviewed and given the necessary approval(s) by the Regulatory Authority (where required) and by the Ethics Committee(s)	**Egypt**

I. STATEMENT OF THE THIRD COUNTRY DATA PROVIDER

I.1	I confirm that /I confirm on behalf of the Third country data provider, sponsor or marketing authorisation holder that: • the information provided is correct and complete as of the date of submission; • the clinical trial will be conducted in accordance with the protocol; and • the clinical trial will be conducted, and adverse reactions and result-related information will be reported, in accordance with the applicable legislation.

ENDNOTES

[1] International Standard Randomised Controlled Trial Number. Sponsors may wish to use an International Standardised Random Controlled Trial Number (ISRCTN) to identify their trial in addition to the EudraCT number; for instance if their trial is part of a multinational trial with sites outside the Community. They can obtain the number and guidance from the Current Controlled Trials website http://www.controlled-trials.com/isrctn to which there is a link from the EudraCT database website http://eudract.ema.europa.eu. When available they should provide it in Section A.5 of the form.
[2] US National Clinical Trial (NCT) Numbers required on the FDA clinical trial application form.
[3] The contact point should give functional information rather than details of one "person", in order to avoid the need for update and maintenance of these contact details.
[4] Available from the Summary of Product Characteristics (SmPC)
[5] According to the Community register on orphan medicinal products (Regulation (EC) n° 141/2000): http://ec.europa.eu/enterprise/pharmaceuticals/register/index.htm
[6] To be provided only when there is no trade name. This is a code designated by the sponsor which represents the name routinely used by the sponsor to identify the product in the CT documentation. For example, a code may be used for combinations of drugs or drugs and devices.
[7] Chemical Abstracts Service.
[8] The mode of action should briefly describe the chemical, biochemical, immunological or biological means the IMP uses to effect its pharmaceutical action.
[9] In the case of healthy volunteer trials, the intended indication for the product under development should be provided.
[10] Applicants are encouraged to provide the MedDRA lower level term if applicable and classification code. These can be accessed from the EMA EudraCT website (http://eudract.ema.europa.eu/).
[11] Points to consider on the calculation and reporting of the prevalence of a condition for Orphan drug designation: COM/436/01 (http://www.ema.europa.eu/htms/human/orphans/intro.htm).
[12] The protocol will usually identify a single primary end point but there may be a co-primary end point in some cases and/or a number of secondary end points.
[13] The descriptions of the trial types provided are those recommended in preference to Phases. See page 5 of Community guideline CPMP/ICH/291/95. The development of a new indication after initial approval of a medicine should be considered as a new development plan.
[14] From the first inclusion until the last visit of the last subject.
[15] These numbers will be initial estimates. Applicants will not be required to update this information nor do they constitute an authorisation or restriction on the inclusion of these numbers of patients in the trial. The numbers of subjects whose inclusion is authorised are those set out in the authorised version of the protocol, or subsequent authorised amendments.