



Project Plan

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Organization



Kompetenznetz niedergelassener
Dermatologen Schweiz

Principal Investigator

PD Dr. Dr. med. Ahmad Jalili

Coordination

Vahid Djamei



**Responsible for design,
conduct, output**

**In collaboration
with**



Sites



Open to all dermatological private clinics in Switzerland

Clinical Research organisation

**Institute for Health Services Research in
Dermatology and Nursing (IVDP)**

Prof. Matthias Augustin, Hamburg

Financial support

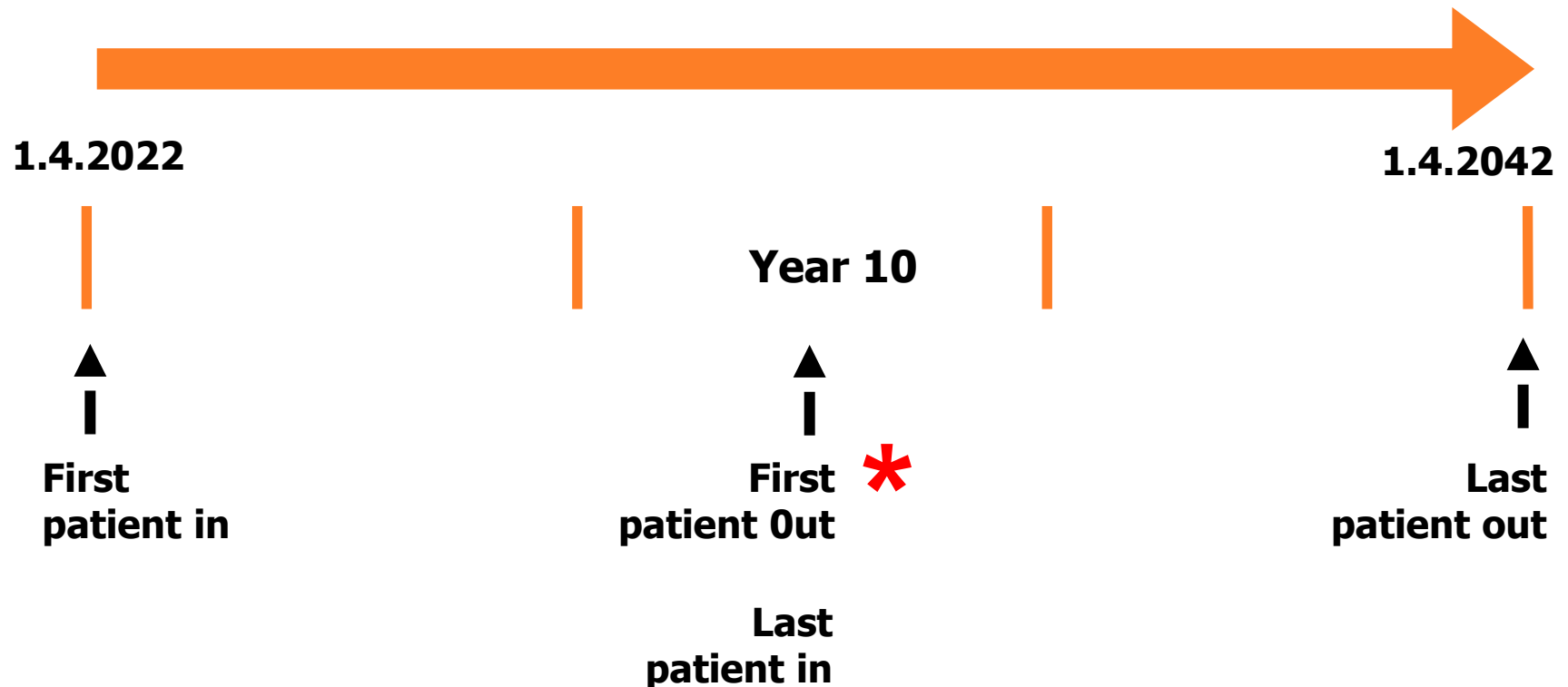
Pharmaceutical companies

Study Design

- **Registry established as non-interventional investigation**
- **Inclusion of patients with Pso & PsoA**
- **Long-term observation**
- **Efficacy of adopted treatment options**
- **Disease burden (quality of life) - progression**
- **Safety**
- **Comorbidities**

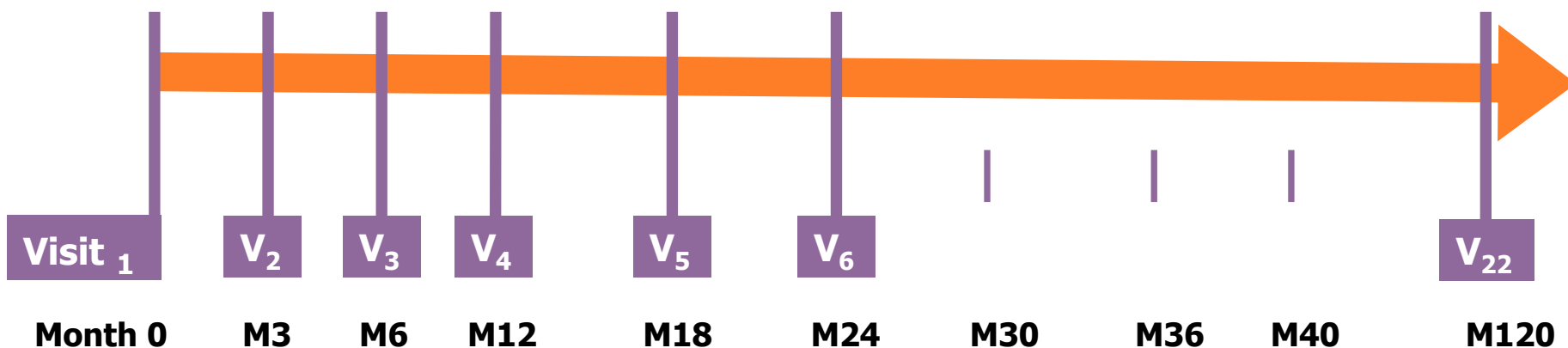
Course of study

10 Years	course of study	* course of study can be extended
30 Patients	Minimum number of Inclusions year	

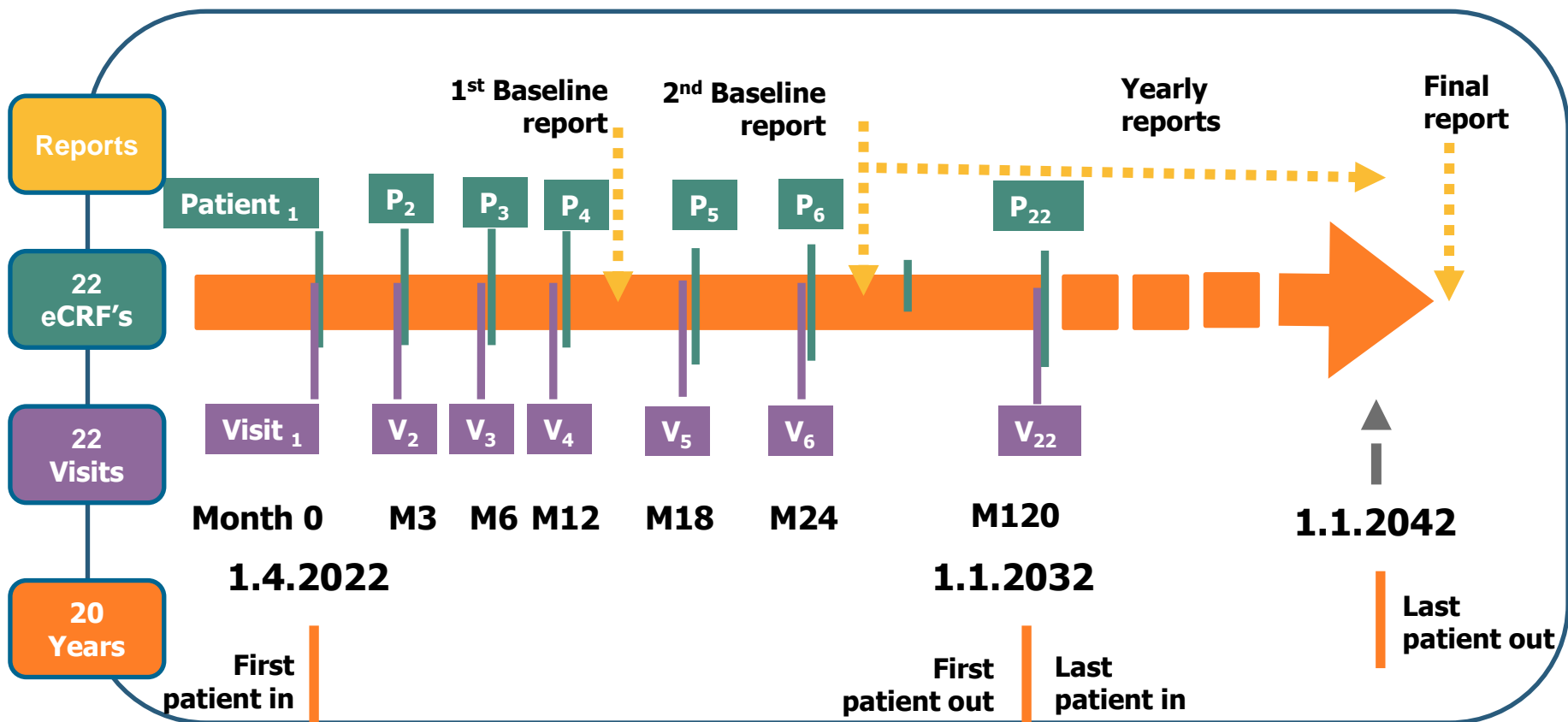


Visit plan

22 Visits	Physical patients visits	22 Doctor Online CRF's
	1 Inclusion visit 21 Follow-up visits	1 Inclusion CRF 21 Follow-up CRF's



Overview



Doctor CRF

Visit	Date of visit *	Month ▾	/ DD / YYYY *					i
Subject ID	In Project ID	Gender	Age	Inclusion	Page	Site	Status	
					1 / 11			

1. Patient information and declaration of consent

Please pass the patient information on to the patient and collect the declaration of consent.

Information for the physician in charge:

- The fax with the declaration of consent is to be sent directly to the data protection officer at Cvderm in charge of patient data and the pseudonymised patient number (ID).
- All further data transmissions are based solely on the patient number (ID) - please do not enter any patient identification features (DOB, name) in the CRF.
- Any queries the patient may have are only made by stating the patient number (ID).

2. In/exclusion criteria

Age ≥ 18 Years

Yes No

Diagnosis

Clinically proven psoriasis vulgaris with or without arthritis.

Yes No

Treatment

Initial application of planned system therapeutic or biologics (other previous therapies irrelevant)

Yes No

Understanding

The patient understands the survey and is expected to be able to fill in the questionnaire.

Yes No

Consent

The patient has provided written consent.

Yes No

The patient can only be included in the trial if all the inclusion criteria have been fulfilled and none of the exclusion criteria apply.

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Doctor CRF

Visit

Subject ID	In Project ID	Gender	Age	Date of Inclusion	Page	Site	Status
					6 / 11		

8. Dermatological status II: Psoriasis Area and Severity Index – PASI

Now please ascertain the PASI with the patient (Psoriasis Area and Severity Index)

Manifestation of efflorescences:

0 = none 1 = slight 2 = medium 3 = strong 4 = very strong

1) Severity of psoriatic lesions

Erythema - Head

0 1 2 3 4

Erythema - Body

0 1 2 3 4

Erythema - Arms

0 1 2 3 4

Erythema - Legs

0 1 2 3 4

Infiltration - Head

0 1 2 3 4

Infiltration - Body

0 1 2 3 4

Infiltration - Arms

0 1 2 3 4

Infiltration - Legs

0 1 2 3 4

Desquamation - Head

0 1 2 3 4

Desquamation - Body

0 1 2 3 4

Desquamation - Arms

0 1 2 3 4

Desquamation - Legs

0 1 2 3 4

2) Affection of body surface

Head

- 0 = None
 1 = <10%
 2 = 10-29%
 3 = 30-49%
 4 = 50-69%
 5 = 70-89%
 6 = 90-100%

Body

- 0 = None
 1 = <10%
 2 = 10-29%
 3 = 30-49%
 4 = 50-69%
 5 = 70-89%
 6 = 90-100%

Arms

- 0 = None
 1 = <10%
 2 = 10-29%
 3 = 30-49%
 4 = 50-69%
 5 = 70-89%
 6 = 90-100%

Legs

- 0 = None
 1 = <10%
 2 = 10-29%
 3 = 30-49%
 4 = 50-69%
 5 = 70-89%
 6 = 90-100%

Doctor CRF

Visit



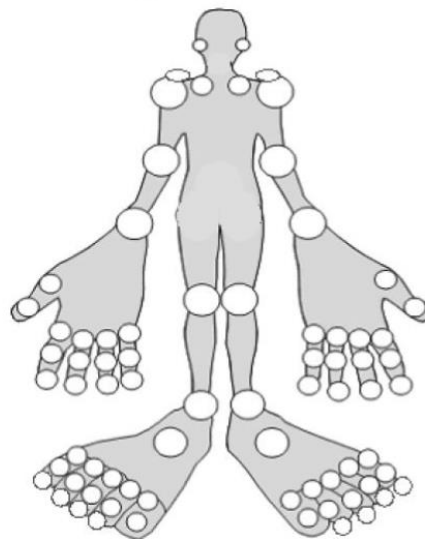
Subject ID	In Project ID	Gender	Age	Date of Inclusion	Page	Site	Status
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	11 / 11	<input type="text"/>	<input type="text"/>

11. Additional sheet - Status of psoriatic arthritis

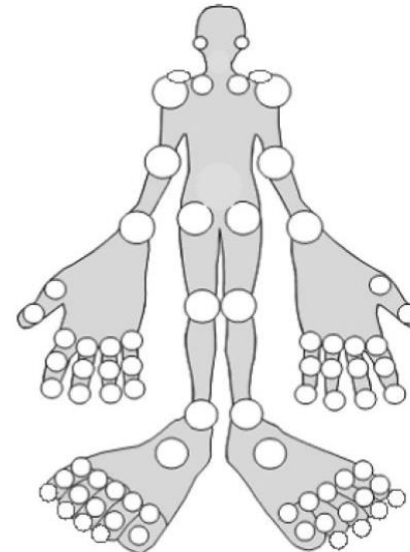
Please only fill out in case of joint discomfort

Current joint status - Please mark the swollen and tender joints.

Swollen



Tender



If you have not marked anything:

- None of these 74 joints are swollen
- None of these 76 joints are painful

Does the patient have these characteristics?

Rheumatic nodule:

- Yes No

Morning stiffness:

- Yes No

Patient CRF

Visit



Subject ID	In Project ID	Gender	Age	Inclusion	Page	Site	Status
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	6 / 12	<input type="text"/>	<input type="text"/>

V. Dermatological Life Quality Index (DLQI)

The aim of this questionnaire is to measure how much your skin problem has affected your life OVER THE LAST WEEK. Please tick one box for each question. If a statement does not apply to you at all, please mark "not relevant".

	Very much	A lot	A little	Not at all	Not relevant
1. Over the last week, how itchy, sore, painful or stinging has your skin been?	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Over the last week, how embarrassed or self-conscious have you been because of your skin?	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Over the last week, how much has your skin interfered with you going shopping or looking after your home or garden?	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Over the last week, how much has your skin influenced the clothes you wear?	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Over the last week, how much has your skin affected any social or leisure activities?	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. Over the last week, how much has your skin made it difficult for you to do any sport?	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	Yes	No	Not relevant		
7. Over the last week, has your skin prevented you from working or studying?	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>		
	Very much	A lot	A little	Not at all	Not relevant
8. Over the last week, how much has your skin created problems with your partner or any of your close friends or relatives?	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. Over the last week, how much has your skin caused any sexual difficulties?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
10. Over the last week, how much of a problem has the treatment for your skin been, for example by making your home messy, or by taking up time?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

Your DLQI Score

13