

## Establishment of a Nationwide Patient Database for Clinical Trial Recruitment in Dermatology: Concept and Patient Characteristics

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Clinical trials are essential for the advancement of medical knowledge; they have revolutionized treatment options (1). Although the cost of conducting clinical trials has risen in recent years (2), they are considered the gold standard for advancing patient care. Patients who choose to participate may find the frequent study visits demanding, but they also benefit from participating in clinical trials. They often receive a higher degree of attention to symptoms. Patients are also provided access to new treatments not yet available to the general public, and in the process of trial participation, they often gain a deeper understanding of their disease (3, 4). In spite of such tangible benefits, recruitment to clinical trials often proves difficult.

Studies have reported patient recruitment to be less than half of the pre-specified number in clinical trials (5, 6). Consequences of poor patient recruitment include underpowered studies, which, in turn, may necessitate a costly extension of the trial (7). In addition, recruitment from specific patient groups or regions may prove difficult, potentially complicating the generalizability of the results of the trial (8). Successful recruitment of patients is therefore considered one of the most challenging aspects of conducting clinical trials (9).

To date, recruitment of patients for clinical trials has been based mainly on physicians' spontaneous recruitment during routine work, e.g. in a busy clinical setting. Commercial patient recruitment programmes have also been initiated, but alternatives to this process are still needed to improve the selective recruitment processes in future clinical trials.

We report here the Trial Nation database, a nationwide database recently established to enhance recruitment to clinical trials in dermatology in Denmark. Trial Nation is a public-private partnership that provides a single, national entry point for life science companies, patient organizations and clinical researchers who wish to sponsor, participate in, or conduct clinical trials in Denmark ([www.trialnation.dk](http://www.trialnation.dk); accessed 12 September 2020). The aim of the Trial Nation database is to create an easily accessible registry of patients who have expressed an a priori interest in clinical trials, i.e. a registry of potential volunteers for trial participation.

Dermatology patients are invited to join the volunteer database by a healthcare professional during routine visits to hospital. Those who decide to join the registry will receive an electronic informed consent form and questionnaire about their skin disease. Patients with psoriasis and atopic dermatitis have been included initially. Future initiatives include expanding recruitment to patients with other dermatological diseases.

The questionnaire includes a selection of relevant variables reflecting selection criteria for prototypes of clinical trials on these indications. The demographics of the patients in the database are shown in **Table I**. The variables include disease distribution, current and prior treatments, and presence of relevant comorbidities (arthritis, asthma, diabetes, coronary heart disease and hypertension). Information regarding prior skin biopsies and blood analysis are also obtained.

Other technical solutions and alternative trial designs have been proposed, but several studies highlight the advantages of investing in maintaining and creating a cross-organizational and national recruitment database (10–13). The Trial Nation database includes an increasing number of potential research volunteers who can easily be contacted and contribute to the advancement of patient care and medical knowledge.

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**Table I. Demographics of patients in the Trial Nation database**

Characteristics			
Total participants, <i>n</i>	745		
Atopic dermatitis, <i>n</i> (%)	142 (19.1)		
Psoriasis, <i>n</i> (%)	602 (80.9)		
Age, years, mean (SD)	46.65 (15.72)		
Weight, kg, mean (SD)	84.85 (22.13)		
Height, cm, mean (SD)	173.41 (13.25)		
Psoriasis, <i>n</i> (%)		Atopic dermatitis, <i>n</i> (%)	
Family history			
Yes	262 (43.5)	Yes	57 (40.1)
No	273 (45.3)	No	69 (48.6)
Do not know	60 (9.9)	Do not know	16 (11.3)
Age at diagnosis, years			
<20	271 (45.0)	<5	86 (60.6)
20–40	231 (38.3)	5–10	20 (14.1)
>40	100 (16.6)	>5	36 (25.3)
Prior consultations			
General practitioner	385 (63.9)	General practitioner	115 (80.9)
Private practice dermatologist	536 (89.0)	Private practice dermatologist	126 (88.7)
Hospital employed dermatologist	538 (89.4)	Hospital employed dermatologist	128 (90.1)
Consultations during the last 12 months			
1	63 (10.4)	1	5 (3.5)
2	61 (10.1)	2	14 (9.8)
3	87 (14.5)	3	15 (10.5)
>4	391 (64.9)	>4	108 (76.1)
Sick leave days due to psoriasis last 12 months			
0	470 (78.1)	0	72 (50.1)
1–3	41 (6.8)	1–3	16 (11.3)
>3	91 (15.1)	>3	54 (38.0)
Prior and current treatments			
Topical corticosteroids	571 (94.9)	Topical corticosteroids	139 (97.8)
Moisturizing creams	482 (80.1)	Moisturizing creams	135 (95.1)
UV therapy	453 (72.2)	UV therapy	89 (62.7)
Potassium permanganate baths	113 (18.7)	Potassium permanganate baths	74 (52.1)
Biological treatment	294 (48.8)	Biological treatment	21 (14.8)
Other oral treatment	82 (13.6)	Other oral treatment	95 (66.9)
Tar	234 (38.8)	Tacrolimus	77 (54.2)
Climate therapy	87 (14.4)	Pimecrolimus	50 (35.2)
Methotrexate	411 (68.2)	Antibiotics	76 (53.1)
Acitretin	102 (16.9)	Oral prednisolone	63 (44.4)
Comorbidities			
Yes	187 (31.1)	Yes	43 (30.2)
No	395 (66.1)	No	93 (65.5)
Missing information	20 (3.3)	Missing information	6 (4.2)
Blood analysis			
Yes	499 (82.8)	Yes	102 (71.8)
No	78 (12.9)	No	27 (19.0)
Do not know	25 (4.2)	Do not know	13 (9.1)
Skin biopsy			
Yes	168 (27.9)	Yes	42 (29.4)
No	344 (57.2)	No	82 (57.7)
Do not know	90 (14.9)	Do not know	18 (12.6)
Disease-specific variables			
Psoriatic arthritis			
Yes	154 (25.6)	Yes	82 (57.7)
No	408 (67.7)	No	51 (35.95)
Do not know	40 (6.6)	Do not know	9 (6.3)
Coronary heart disease			
Yes	42 (6.9)	Yes	56 (39.4)
No	554 (92)	No	74 (52.1)
Do not know	6 (0.9)	Do not know	12 (8.5)
Diabetes, <i>n</i> (%)			
Yes	45 (7.5)	Yes	93 (65.5)
No	555 (92.2)	No	44 (30.9)
Do not know	2 (0.3)	Do not know	5 (3.5)
Hypercholesterolaemia			
Yes	148 (24.6)	Yes	69 (48.6)
No	432 (71.8)	No	59 (41.5)
Do not know	22 (3.7)	Do not know	14 (9.8)
Depression			
Yes	116 (19.2)	Yes	60 (42.2)
No	475 (78.9)	No	52 (36.6)
Do not know	11 (1.8)	Do not know	30 (21.1)
Psoriasis distribution			
Nail	295 (49.0)		
Hair	391 (64.9)		
Skin folds	134 (22.2)		
Hands	252 (41.9)		
Feet	200 (33.3)		
Body/arm-legs	536 (89.0)		

UV: ultraviolet.

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