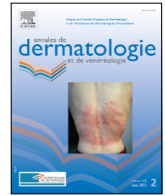




Available online at
ScienceDirect
www.sciencedirect.com

Elsevier Masson France
EM|consulte
www.em-consulte.com/en



Perspective/Opinion

Promoting clinical research in community-based practice: Threats and opportunities

F. Poizeau^{a,b,*}, A. Maruani^{a,c,d}, D. Staumont-Sallé^{a,e}, N. Jouan^{a,f}, S. Ly^{g,h}, M. Schollhammer^{f,i}, M. Reverte^j, C. Dibao-Dina^{d,k}, T.-A. Duong^l, B. Matard^m, D. Penso-Assathianyⁿ, A. Dupuy^b, M. Carriot^o, J.-F. Seï^{a,p}, F. Corgibet^a, B. Guillot^{a,q}, S. Barbarot^{a,r}, S. Leducq^{a,s}, A. Bertolotti^{a,t}, J. Tannous^a, G. Chaby^{a,u}, D. Jullien^{a,v}, E. Pépin^{a,w}, G. Quéreux^x, M. Beylot-Barry^{a,y}, O. Chosidow^{a,z}, on behalf of the Centre of Evidence of the French Society of Dermatology

^a Centre de Preuves en Dermatologie, Société Française de Dermatologie, 10 Cité Malesherbes, 75009 Paris, France

^b Univ Rennes, CHU Rennes, Inserm, EHESP, Irset (Institut de recherche en santé, environnement et travail)-UMR_S 1085, F-35000 Rennes, France

^c CHRU de Tours, Service de Dermatologie, Unité de Dermatologie pédiatrique, 37000 Tours, France

^d Universités de Tours et de Nantes, Inserm 1246-SPHERE, Nantes, France

^e CHU Lille, Service de Dermatologie, Univ Lille, INSERM U1286, Lille Inflammation Translational Research Institute (INFINITE) F-59000, Lille, France

^f Cabinet de Dermatologie, 29200 Brest, France

^g Cabinet de Dermatologie, Gradignan, France

^h Service de Dermatologie, Hôpital St André, Bordeaux, France

ⁱ Service de Dermatologie, CHU Brest, Brest, France

^j Cabinet de Dermatologie, 83120 Sainte-Maxime, France

^k Département Universitaire de Médecine Générale, Université de Tours, Tours, France

^l Service de dermatologie générale et oncologique, CHU Ambroise Paré, Boulogne-Billancourt, France

^m Centre Sabouraud, Hôpital Saint Louis, Paris, France

ⁿ Institut Arthur-Vernes, 36 rue d'Assas, 75006 Paris, France

^o Infirmière puéricultrice de recherche, CIC 1415 de Tours, Tours, France

^p Fédération Française de Formation Continue et d'Évaluation en Dermatologie Vénéréologie

^q Dermatologue, Université de Montpellier, Montpellier, France

^r Nantes Université, Service de Dermatologie, CHU Nantes, INRAE, UMR 1280, PhAN, F-44000 Nantes, France

^s Service de Dermatologie, CHRU Tours, 37000 Tours, France

^t CIC-INSERM1410, Service de Maladies Infectieuses - Dermatologie, CHU de la Réunion, Saint Pierre, La Réunion, France

^u Service de Dermatologie, CHU Amiens, 80000 Amiens, France

^v Hospices Civils de Lyon, Hôpital E. Herriot, Service de Dermatologie, Lyon F-69003; Université Lyon-1, INSERM Unité 1111-CIRI, Lyon F-69007, France

^w Dermatologue, FFFCEDV, Villepreux, France

^x Service de Dermatologie, CHU Nantes, Université de Nantes, CIC 1413, Inserm UMR 1302/EMR6001 INCIT, F-44000 Nantes, France

^y Service de Dermatologie, CHU Bordeaux, INSERM U1312, Bordeaux Institute of Oncology, Univ Bordeaux, Bordeaux, France

^z AP-HP, Hôpital Pitié-Salpêtrière, consultation dermatoses faciales, Paris, France

ARTICLE INFO

Article history:

Received 24 October 2023

Accepted 4 March 2024

Available online 29 April 2024

The involvement of community dermatologists in clinical trials is essential to enable clinical research to address common skin conditions that do not require hospital care. Unfortunately, it is clear that most randomized clinical trials (RCTs) do not include these populations, leading to a lack of evidence and subsequent limitations in the management of common skin diseases.

* Corresponding author at: Service de Dermatologie, CHU Rennes, 2 rue Henri Le Guilloux, 35000 Rennes, France.

E-mail address: florence.poizeau@chu-rennes.fr (F. Poizeau).

<https://doi.org/10.1016/j.annder.2024.103272>

0151-9638/© 2024 The Author(s). Published by Elsevier Masson SAS.

To promote independent clinical research at the community level, a seminar was organized by the Centre of Evidence of the French Society of Dermatology in Paris, France, in January 2023. The speakers were chosen for their involvement in clinical research as community-based dermatologists, general practitioners or nurses, or for their commitment to promoting research in this setting. The first part of the conference focused on the current state of research among community-based practitioners and the identification of threats and opportunities, with the presentation of several studies conducted by community-based practitioners. The second part was a roundtable discussion aimed at providing suggestions

for improving the involvement of community-based dermatologists in clinical research.

1. Threats and opportunities

1.1. Facilitators identified

- Choice of research topic
The research topic should reflect a difficulty encountered in consultations or a question raised in clinical practice, as participation by an independent community practitioner is driven by individual motivation rather than obligation.
- Hospital and academic support
Departments of dermatology and clinical trials units can help determine methodology and regulatory procedures. Involvement of a dermatology resident may encourage completion of a project and writing of an article.
- Dedicated funding
The biannual call for proposals for dermatology research aimed at community-based dermatologists, funded by the French

Society of Dermatology, was designed to promote research in community practice. Two sessions are held each year, with a maximum bi-annual budget of €40,000 to be allocated to one or more projects (<https://www.sfdermato.org/page-18-appels-a-projets-et-bourses-sfd>). Projects are submitted and supported by community-based dermatologists, but may also be supported by a mixed team including hospital members. All types of research are encouraged, including semiology, pathophysiology, public health, epidemiology, and observational or interventional studies. Over the past 10 years, 12 projects have been submitted, 10 of which have been funded for a total of 201,150€ (Table 1).

1.2. Barriers identified

- Lack of time
Explaining the procedure to patients and completing case report forms is a time-consuming process.
- Prevalence of the condition
The condition should be common enough to be encountered in community practice. Conversely, a condition that is too common

Table 1

Summary of projects over a 10-year period funded by the French Society of Dermatology resulting from a biannual call addressed to community-based dermatologists.

Year	Funding amount (€)	Leader	Project
2013 September	40,000	Jean-Michel Amici	Defining and recognising locally advanced basal cell carcinoma (Amici et al. 2015, https://doi.org/10.1684/ejd.2015.2641)
2014 March	0		
September	5,000 5,000	Sandra Ly Fabien Pelletier	GENI-PSO: Feasibility study Pilot monocentric study on the effects of capsaicin patch in the treatment of provoked vestibulodynia
2015 March	0		
September	33,000	Sandra Ly	GENIPSO: a French prospective study assessing instantaneous prevalence, clinical features and impact on quality of life of genital psoriasis among patients consulting for psoriasis (Larsabal et al. 2019, https://doi.org/10.1111/bjd.17147)
2016 March	0		
September	0		
2017 March	30,000	Pascal Reygagne	Pathophysiology of Frontal Fibrosing Alopecia
September	0		
2018 March	20,000	Jean-Michel Amici	CITY-PSO: Prescribing behaviour of French private-practice dermatologists in psoriasis management: An observational, multicentre, cross-sectional study (Amici et al. 2022, https://doi.org/10.1016/j.annder.2022.01.001)
September	0		
2019 March	0		
September	0		
2020 March	16,000	Jean-François Sei	Melalib. Cutaneous Melanoma in France Diagnosed by 491 office-based dermatologists during the Year 2020: care pathways, characteristics of incident melanomas, and treatment modalities.
September	0		
2021 March	0		
September	16,000	Nicole Jouan	Isolib. Prospective observational study on isotretinoin for acne in France in 2021 at the office: dosage, side effects, treatment discontinuation.
2022 March	21,290 14,860	Jean-Michel Amici Dominique Penso-Assathiany	AdT-Obs. Adherence and therapeutic compliance in the management of psoriasis. Wearing gloves and hygiene practices during Covid-19 pandemic.
September	0		
2023 March	5,120	Valérie Doriry-Vuong	Most relevant indications in teledermatology through a Delphi method.

may lead to excessive investment if all cases are systematically included.

- Lack of financial compensation (as remuneration is linked to care in private practice)
- Representativeness of participants
Only a small group of community dermatologists participate in clinical research, resulting in selection bias.

2. Suggestions

2.1. Timesaving

- Simplify the methodology where possible by requiring only a single or very few visits and by creating a short, easy to complete case report form.
- Involve clinical research associates

2.2. Determination of financial compensation

Financial compensation commensurate with the time spent and the number of patients enrolled may encourage greater participation. This should be considered when planning the research budget.

2.3. Selecting a clinical research investigator

A referent within associations of community dermatologists could play an advisory role. Contact could be made with the French Society of Dermatology to provide assistance with administrative procedures, regulatory steps, and ethics committee submissions as needed.

2.4. Making pragmatic design decisions

- The use of a placebo or experimental treatment can be complex because of the available distribution network and stocking of the study products. It is preferable to use a drug that is available in pharmacies; alternatively, access to hospital pharmacies should be possible.
- Cluster randomized trials (where appropriate), in which investigators rather than patients are randomized, have the advantage of avoiding the need to randomize patients in community practices.

3. Conclusion

Increased involvement of community-based dermatologists in clinical research is an important goal for the dermatology community to improve the statistical power and representativeness of studies. Projects conducted by community-based dermatologists and collaboration with community-based dermatologists for hospital clinical research programs are both needed to advance medical knowledge and improve patient care.

The involvement of community-based dermatologists in clinical trials is essential to enable clinical research to address common cutaneous diseases that do not require hospital care. It is unfortunately clear that most randomized clinical trials (RCTs) do not include these populations, leading to a lack of evidence and subsequent limitations in the management of common skin diseases.

To promote independent clinical research at community level, a seminar was organized in January 2023 by the Centre of Evidence of the French Society of Dermatology in Paris, France. The speakers

were chosen for their involvement in clinical research as community-based dermatologists, general practitioners, or nurses, or for their commitment to promoting research in this setting. The first part of the conference focused on the current state of research among community-based practitioners and the identification of threats and opportunities, with the presentation of several studies carried out by community-based practitioners. The second part was a round-table discussion aiming at making proposals to improve the involvement of community-based dermatologists in clinical research.

CRedit authorship contribution statement

F. Poizeau: Data curation, Writing – original draft, Writing – review & editing, Visualization, Validation, Project administration, Software. **A. Maruani:** Writing – review & editing, Validation, Supervision, Resources. **D. Staumont-Sallé:** Writing – review & editing, Validation. **N. Jouan:** Writing – review & editing, Validation. **S. Ly:** Writing – review & editing, Validation. **M. Schollhammer:** Writing – review & editing, Validation. **M. Reverte:** Writing – review & editing, Validation. **C. Dibao-Dina:** Writing – review & editing, Validation. **T.-A. Duong:** Writing – review & editing, Validation. **B. Matard:** Writing – review & editing, Validation. **D. Penso-Assathiany:** Writing – review & editing, Validation. **A. Dupuy:** Writing – review & editing, Validation. **M. Carriot:** Writing – review & editing, Validation. **J.-F. Seï:** Writing – review & editing, Validation. **F. Corgibet:** Writing – review & editing, Validation. **B. Guillot:** Writing – review & editing, Validation. **S. Barbarot:** Writing – review & editing, Validation. **S. Leducq:** Writing – review & editing, Validation. **A. Bertolotti:** Writing – review & editing, Validation. **J. Tannous:** Writing – review & editing, Validation. **G. Chaby:** Writing – review & editing, Validation. **D. Jullien:** Writing – review & editing, Validation. **E. Pépin:** Writing – review & editing, Validation. **G. Quéreux:** Writing – review & editing, Validation. **M. Beylot-Barry:** Conceptualization, Funding acquisition, Validation, Supervision. **O. Chosidow:** Conceptualization, Funding acquisition, Validation, Supervision, Resources.

Funding sources

Centre of Evidence of The French Society of Dermatology.

Conflicts of interest

Poizeau: Consultant for Bristol Myers Squibb and Novartis.

Staumont-Sallé: Investigator for Abbvie, Almirall, Amgen/Celgène, Astra-Zeneca, Galderma, Eli Lilly, Leo Pharma, Novartis, Sanofi-Regeneron; Consultant for Abbvie, Almirall, Astra-Zeneca, Eli Lilly, Leo Pharma, Janssen, Novartis, Sanofi, Pfizer; Speaker for Abbvie, Eli Lilly, Janssen, Novartis, Pfizer, Sanofi, UCB.

Corgibet: Consultant for Pfizer.

Barbarot: Investigator for Almirall, Sanofi-Genzyme, Abbvie, Galderma, Leo-Pharma, Eli Lilly; Speaker for Astrazeneca, Almirall, Sanofi-Genzyme, Abbvie, Galderma, Alexion, Novartis, Janssen, Leo-Pharma, Pfizer, Eli Lilly, UCB Pharma.

Chaby: Speaker for Novartis, Léo-Pharma, Janssen, Sanofi; Consultant for Abbvie, Pfizer, UCB-Pharma, Janssen; Investigator for Léo-Pharma, Abbvie, Pfizer.

Beylot-Barry: Investigator for Novartis, Sanofi, MSD, Regeneron, Boehringer, Tellomak; Consultant for Kyowa, Recordati, Janssen; Speaker for Abbvie, Janssen, Novartis, Recordati, Kyowa, Takeda.

Chosidow: Investigator for Medicines and Development for Global Health; Consultant for Medicines and Development for Global Health, Greentech; Speaker for Sun Pharma Maroc.

Maruani, Jouan, Ly, Schollhammer, Reverte, Dibao-Dina, Duong, Matard, Penso-Assathiany, Dupuy, Carriot, Sei, Guillot, Leducq, Bertolotti, Tannous, Jullien, Pépin, Quéreux: no disclosure.

Acknowledgements

We would like to thank Angela Verdier, SARL L'Auracoise, for the English-language revision.