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## INTRODUCTION

Rheumatological diseases are a heterogeneous group of disorders, united by chronic inflammatory processes<sup>1</sup>. The lack of adequate treatments and the occurrence of adverse drug reactions have led to the need for alternative strategies, including nutrition. Diet can influence inflammatory processes and the occurrence of comorbidities in the rheumatological conditions<sup>2</sup>. Among dietary strategies, a prominent role is played by dietary supplements, because of the belief that they can be a valuable aid, although not without adverse effects. However, the lack of data on their consumption hampers risk assessment.

## AIM OF THE PROJECT

Collect accurate information on the dietary supplement use in rheumatology to fill the existing gap in this field and enable risk characterization. A survey-based cross-sectional study “IntegraRE” has been designed to investigate:



- **PHASE 1.** Rheumatologists' knowledge, attitudes, and recommendations to patients regarding dietary supplements.
- **PHASE 2.** Intake of dietary supplements by **patients**, focusing on the specific product, the unit consumed and the motivation for consumption.

## EXPERIMENTAL DESIGN

### PHASE 1 AND PHASE 2 INCLUSION CRITERIA

- ✓ Rheumatologist practicing in Italian public and private healthcare facilities (*Phase 1 only*)
- ✓ Patient who requests a specialist examination by a Phase 1 rheumatologist (*Phase 2 only*)
- ✓ Resident in Italy, know and speak the Italian language
- ✓ Voluntarily join the study
- ✓ Accept the informed consent

### Population

- 1,134 rheumatologists distributed as follows:
  - North 454 (40%)
  - Center 250 (22%)
  - South 271 (24%)
  - Islands 159 (14%)
- Nationally representative sample at least **287 physicians**<sup>3</sup>.

### PHASE 1

#### Data collection

- Online questionnaire of 59 questions available for 6 months (Fig. 1)
- Information on sociodemographic variables, lifestyle, knowledge, consumption, and clinical practice of supplements
- Confidentiality ensured by a unique alphanumeric code
- Reliability of the questionnaire tested with test-retest.



Figure 1. IntegraRE online questionnaire

### WORKSHOP

At the Italian National Institute of Health (ISS), in collaboration with CReI (Collegio Reumatologi Italiani), an event, aimed at rheumatologists, will be organized to raise awareness about supplements.

During the workshop the following will be presented:

- preliminary data collected in Phase 1
- objectives and management of Phase 2

### Population

- Patients who request a visit to the Phase 1 rheumatologists
- At least **2,000 patients**<sup>4</sup> will be enrolled stratified at regional level (Fig. 2) considering the total number of rheumatologists and their distribution in Italy
- Minimum number of questionnaires was set equal to 30.

### PHASE 2

#### Data collection

- Self-administered questionnaire (35 questions), devoid of identifying elements, to be completed in the waiting room and available for 12 months
- Information on sociodemographic variables, lifestyle, knowledge, consumption of supplements will be requested
- The completed questionnaires will be collected and sent periodically by the physician to ISS
- The reliability of the questionnaire will be evaluated by means of internal consistency test.

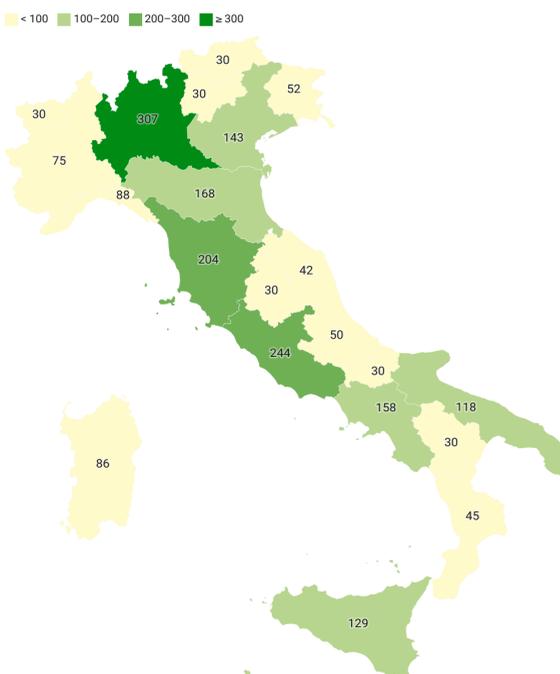


Figure 2. Number of patient's questionnaire collected at regional level

## EXPECTED RESULTS

- Understanding the consumption of dietary supplements in rheumatology and establishing the scientific basis for their use through a literature review.
- Drafting guidelines on the proper use of dietary supplements in rheumatology clinical practice
- Validation of the rheumatologist's questionnaire by extending it to other health professional categories.

## CONCLUSIONS

This survey will allow us to:

- better characterize the risk-benefit ratio of dietary supplements, preserving consumers' health
- increase people's awareness of dietary supplements effects, leading to their conscious and safe use.



### REFERENCES

[1] Oliviero et al., Giornale italiano di farmacoeconomia e farmacoutilizzazione 2017; 9(1):107-111. [2] Henrotin et al., Current rheumatology reports 2018; 20(11):72. [3] Armitage P, Berry G. Statistica Medica, metodi statistici per la ricerca in Medicina, Terza Edizione. Milano: Mc Graw-Hill Libri Italia 1996; 6:199-210. [4] EFSA, EFSA Journal 2009; 7(12):1435.