

Type:
Nutrition

Geography:
Europe

Study Type:
Phase II/III

Client:
Biotechnology
Company

PROJECT TITLE:

“A randomized, placebo-controlled, double-blind study to assess the effect of XXX on blood pressure in subjects with moderately elevated blood pressure”

Objective

Recruit 400 high normal/grade 1 hypertension patient goal in Bulgaria, Poland, Hungary & France for randomized study of a (Hypertension) food supplement

Study Challenges:

- 1) Difficult to recruit patients who meet all eligibility criteria. There is also a short timeline before these patients use/are prescribed medical treatments.
- 2) Relatively short enrolment time vs. high study recruitment target
- 3) Low market confidence in solely nutritional treatments for Hypertension
- 4) High barrier to entry for patients due to the high contact time despite having minor symptoms and ‘easy’ medical alternatives

Excelya Solutions:

- 1) We utilized our network of established sites, with whom we have a good working relationship/that had a genuine interest in food supplements. This enabled faster start-up and activation.
- 2) Site & patient education: Focused on the positive and natural aspect of using food supplements, low adverse event risk, etc.
- 3) We took proactive steps to reduce the barrier to entry for patients, such as creating a food diary form that is easy for patients to complete.

Key metrics

400
patients
recruited

1st patient in
**achieved on
time**

Impact:

- Study results enabled commercialisation of the product/supported positive marketing claims
- Key study milestones and recruitment goals delivered on time