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Improving health service for European citizens with dementia

universität Witten/Herdecke

Management perspective of a European research project:

Fair authorship allocation and Ethical Committees' approvals

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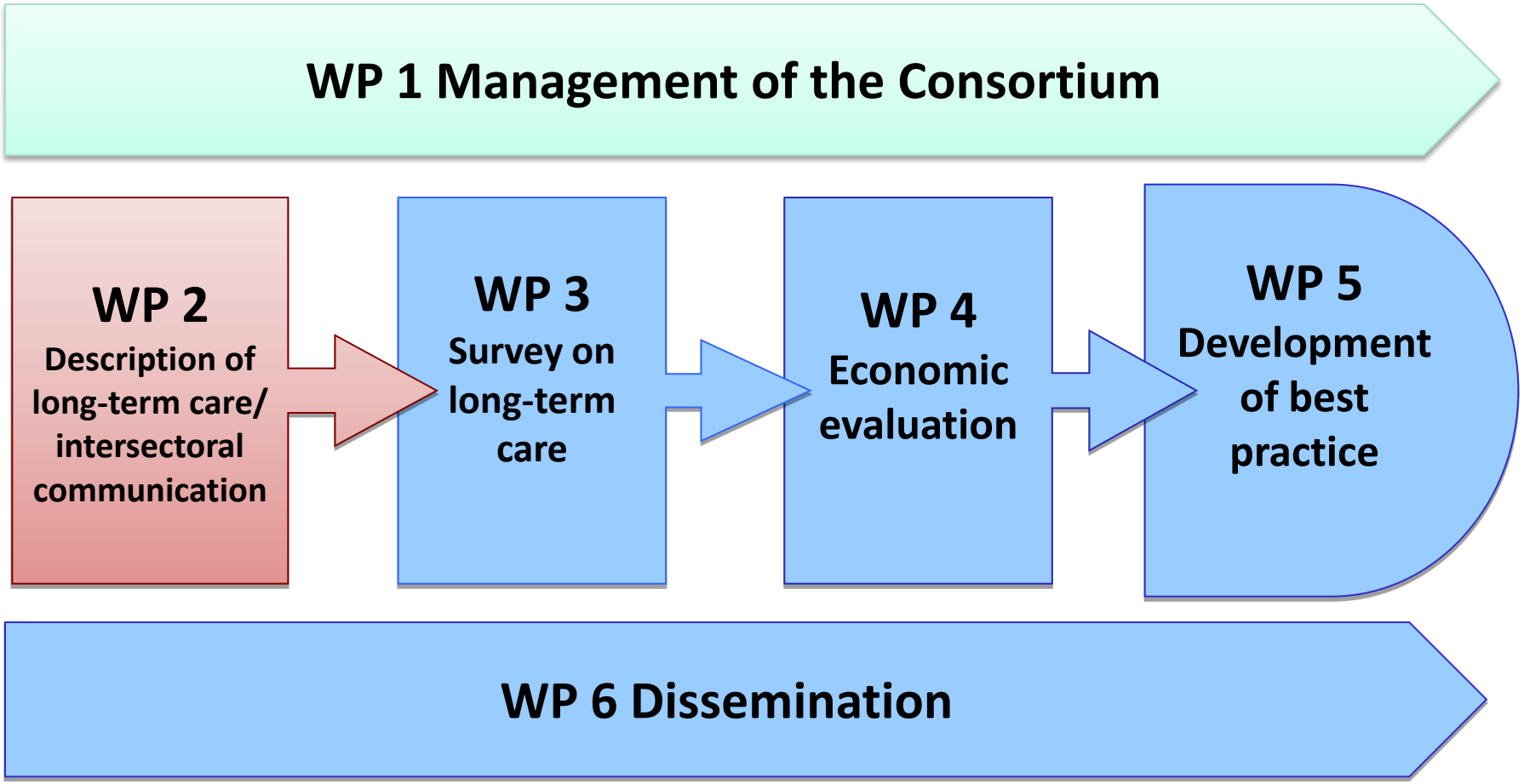
Witten University/Germany on behalf of the RTPC Consortium

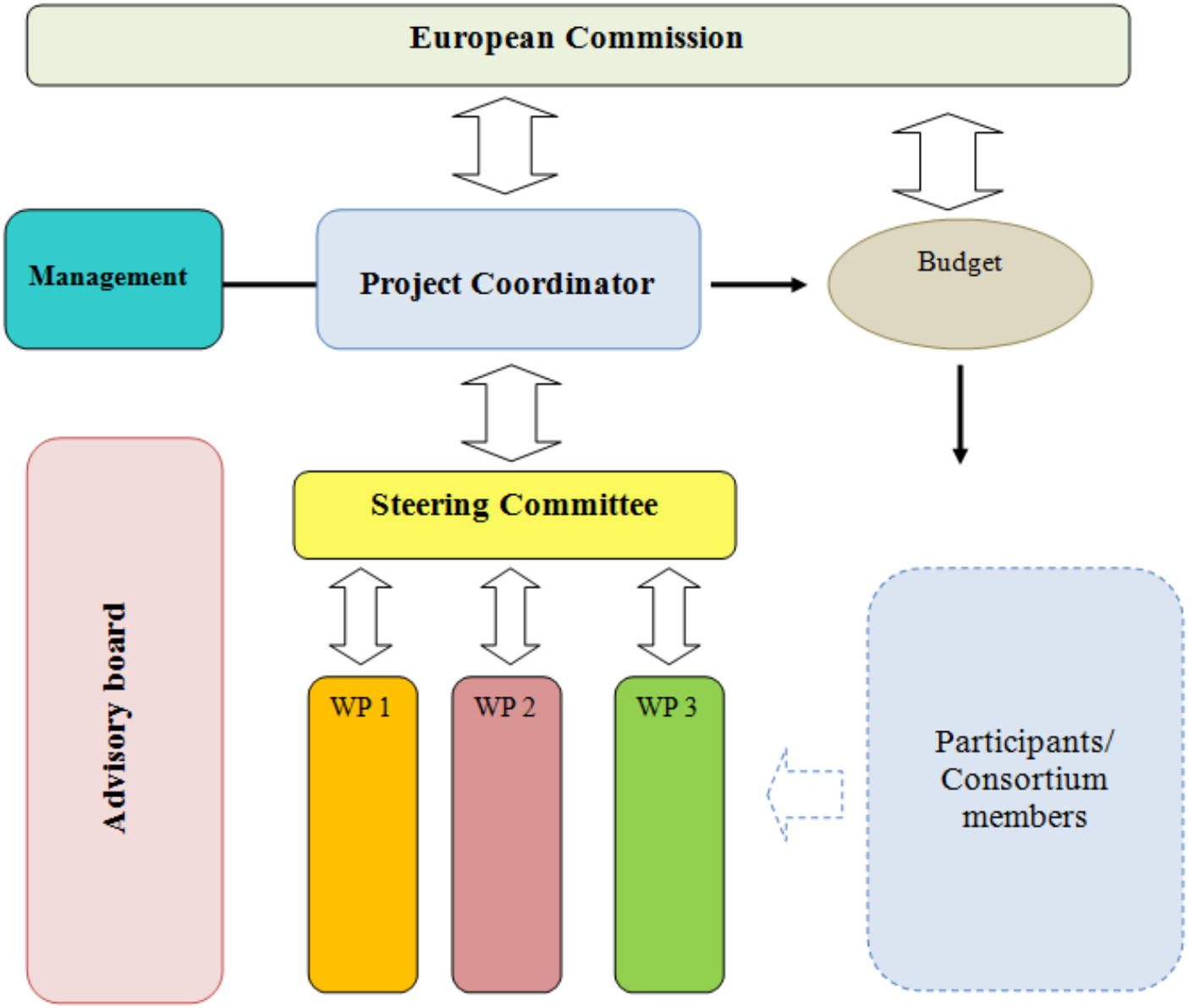
RightTimePlaceCare (RTPC) Project

European multi-center, collaborative research project funded by the EC

- Witten University, Germany (WP1, WP4, WP6)
- Lund University, Sweden (WP2)
- Maastricht University, The Netherlands (WP3)
- Hospital Clínic de Barcelona, Spain (WP5)
- University of Tartu, Estonia (WP5)
- Manchester University, United Kingdom
- University of Turku, Finland
- University of Toulouse, France

Flow of the RTPC project




European Commission
Management
Project Coordinator
Budget
Steering Committee
Advisory board
WP 1
WP 2
WP 3
Participants/
Consortium
members

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Management of a European research project

1. Ensuring timely and qualitative achievement of project results
2. Ensuring risk management
3. Providing timely and efficient administrative and financial control of the project and meeting contractual agreements
4. Supporting the Project Coordinator, Steering Committee and Work Package Leaders
5. **Coordinating the management of knowledge and innovation-related activities**

Two important management tasks:

- Fair authorship allocation/ publication strategy
- Ethical Committees' approvals

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Authorship rules and publication strategy

Aims:

Ensuring

- Fair authorship allocation reflecting contribution of each researcher (issue of research ethics)
- Transparency/contributorship
- Preparation of Master and PhD theses

Avoiding

- Overlapping publication activities
- „Slicing“ of data
- „Flooding“ same journals with similar publications

Method for Establishing Authorship in a Multicenter Clinical Trial

David J. Whellan, MD, MHS; Stephen J. Ellis, PhD; William E. Kraus, MD; Katie Hawthorne, MD; Ileana L. Piña, MD; Steven J. Keteyian, PhD; Dalane W. Kitzman, MD; Lawton Cooper, MD; Kerry Lee, PhD; and Christopher M. O'Connor, MD

With the emergence of large multicenter trials over the past 20 years, the numbers of investigators involved and publications resulting from each study have grown exponentially. An efficient, fair, and effective way to establish authorship on study-related manuscripts could diminish conflict among the investigators and help ensure robust and timely dissemination of study results. This article describes a process developed by the investigators in the HF-ACTION (Heart Failure: A Controlled Trial Investigating Outcomes of Exercise Training) trial (ClinicalTrials.gov registration number: NCT00047437) to establish authorship of the manuscripts describing the baseline characteristics, study design, and trial outcomes in an equitable and transparent manner based on objective, quantifiable contributions to the study as a whole. The HF-ACTION investigators developed a scoring system that assigned points to investigators by using the criteria established for enrollment, adherence to the exercise program, data completion, committee service, and other trial efforts. The scoring system has been successfully implemented for baseline manuscripts and has allowed many investigators to participate in the HF-ACTION publication process.

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For author affiliations, see end of text.

In academic medicine, promotion and research funding are generally based on one's academic record, with a steadily growing number of peer-reviewed publications on the curriculum vitae being a common measure of career achievement. This pressure can lead to inappropriate designation of authorship on a manuscript as an "honor" or a "gift," a questionable practice that can raise a red flag about potential research misconduct (1, 2). The emergence of large multicenter clinical trials over the past 20 years has added several layers of complexity—and potential conflict—to this already burdened process. With more institutions and consequently more researchers involved in planning, enrollment, and data acquisition, the list of individuals who contribute substantially, and therefore deserve authorship assignments, grows commensurately. With its 98 investigators and 82 regional centers (67 centers in the United States, 9 in Canada, and 6 in France) and 2331 participants, the HF-ACTION (Heart Failure: A Controlled Trial Investigating Outcomes of Exercise Training) trial (ClinicalTrials.gov registration number: NCT00047437) provided an ideal opportunity to devise and implement a publication plan that would accommodate the complexities of the protocol and at the same time offer an equitable distribution of authorship assignments.

We describe the process through which we constructed our model and the scoring system we devised to assign authorship among the investigators from our group. We set the following goals for our process: 1) reward individuals for their efforts in obtaining funding and organizing trial infrastructure, 2) encourage contributions to the successful conduct of the study, 3) generate new and creative ideas to maximize the use and dissemination of the trial data, 4) ensure that all contributors view the process as fair, and 5) ensure compliance with the internationally accepted guidelines for authorship established by the International Committee of Medical Journal Editors (ICMJE) (3).

See also:

Web-Only
Appendix Table
Conversion of graphics into slides

The Study and Its Organization

The primary objective of the HF-ACTION trial was to establish whether patients with left ventricular systolic dysfunction and New York Heart Association class II to IV symptoms given exercise training in addition to standard care would have a 20% lower rate of death and hospitalization over 2 years than patients who received usual care alone (4). The trial incorporated the general organizational features of phase III therapeutic clinical trials with additional features that address the unique nature of its exercise intervention. This structure included a steering committee, an executive committee, a coordinating center, and 3 core laboratories—a cardiopulmonary exercise (CPX) testing core laboratory, a nuclear core laboratory, and an echocardiography core laboratory (**Figure 1**). The site investigators all served on the steering committee, which made the final scientific decisions for the trial. The executive committee, composed of the steering committee chairperson and vice-chairperson, representatives from the coordinating center (including the principal investigator [PI], co-PI, and statistician), and members of the National Heart, Lung, and Blood Institute (NHLBI) project office, provided day-to-day oversight of the trial and made decisions not requiring full steering committee approval. Appointed by the executive committee, the publications committee, which continues to be active, comprises investigators from individual sites and the coordinating center who expressed an interest in participating on the committee and whose areas of expertise reflect various aspects of the trial (such as statisticians, exercise physiologists, physicians, investigators, and

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Methods:

- Literature based development of **authorship and publication rules/publication strategy**
- Following recommendations of EC and the ICMJE
- Accepted by the Steering Committee

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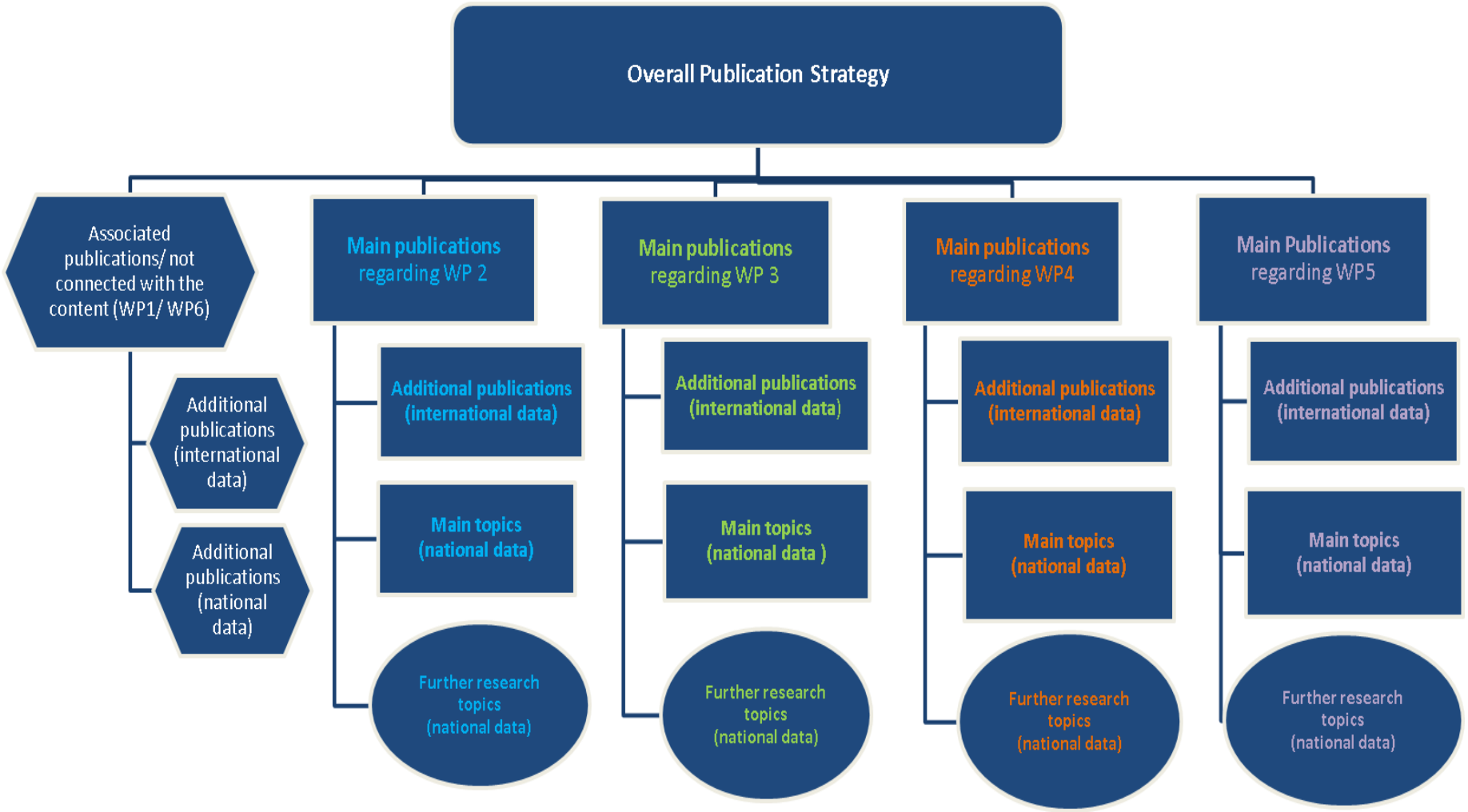
Authorship and publication rules

- Clear criteria for authorship (according to ICMJE)
- Determination of publication topics (main publications/additional publications/national and international)
- Decision-making process
- Order of authors
- Duties and responsibilities of authors/co-authors
- Disputes
- Conferences/congresses
- Format issues


Overall Publication Strategy
Associated publications/ not connected with the content (WP1/ WP6)
Additional publications (international data)
Additional publications (national data)
Main publications regarding WP 2
Additional publications (international data)
Main topics (national data)
Further research topics (national data)
Main publications regarding WP 3
Additional publications (international data)
Main topics (national data)
Further research topics (national data)
Main publications regarding WP4
Additional publications (international data)
Main topics (national data)
Further research topics (national data)
Main Publications regarding WP5
Additional publications (international data)
Main topics (national data)
Further research topics (national data)

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Evaluation:

- Authorship rules will be evaluated at the end of the RTCP project by target/performance comparison
- Consortium members will be interviewed about the applicability of these rules
- Experiences will be reported and will be available for further comparable research projects

Approvals of Ethical Committees

Initial situation:

- Ethical approvals are required for WP2/WP3 from all local Ethical Committees
- Study protocol applicable to all countries has been jointly developed
- Protocols are currently reviewed by local Ethical Committees (8 EU countries)

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- Empirical data indicate different decisional patterns of ethical committees in Europe
- These variations might affect research results
- Research involving people with dementia is increasing
- Only a few studies compare approvals of ethical committees in dementia research
- Alignment of ethical requirements should be promoted across Europe (e.g. regarding informed consent procedure)

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Purpose:

- Ethical approval from each country will be collected for comparison
- Differences will be described and reported
- Impact on the execution of the research protocol will be analysed and described

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Thank you very much for your attention!