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(Cost)-effectiveness of antivirals for influenza-like-illness in primary care: Set-up and progress of the ALIC4E trial in 17 European Countries.

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Background and Aim: Neuraminidase inhibitors decrease illness duration in patients with influenza. However, there has never been a large-scale, publically funded trial assessing clinical and cost-effectiveness of antivirals in routine primary care. We therefore aim to investigate overall benefits and costs of treating patients with influenza-like-illness with antivirals. Secondly, we aim to identify subgroups of patients receiving more, or a particular benefit from antiviral treatment.

Methods: ALIC4E is an open, platform, response-adaptive randomised trial aiming to recruit 4500 patients with influenza-like-illness from 21 primary care Networks in 17 European countries, during three successive influenza seasons. Patients will be treated according to usual primary care practice in their country, with or without Oseltamivir in the first season. In subsequent seasons, a new antiviral might be added resulting in a 3-arm trial. The composite primary outcome will be: return to normal daily activity, with fever, head/muscle ache reduced to a minor problem, or less.

ALIC4E is part of the PREPARE consortium (www.prepare-europe.eu).

Results: In the first year, the Networks were established, approvals have been obtained from local ethical boards and national competent authorities, and patient insurance, medication distribution and all trial logistics and contracts were arranged in the 17 countries: Norway, Sweden, Denmark, Ireland, United Kingdom, Netherlands, Belgium, Switzerland, Lithuania, Poland, France, Spain, Hungary, Romania, Czech Republic, Croatia and Greece. We have found considerable variation in focus and legal, ethical and procedural requirements between these countries. At the start of the influenza season 2016, 12 countries had all requirements in place and started including patients.

Conclusions: The opportunities, barriers and challenges of large-scale, innovative primary care trials in 17 countries, and the trial progress will be further highlighted and discussed.