distributed in the middle of the second semester, from 16 to 19 April 2018 at the end of the sessions of interactive work groups concentrating, for the first time, on pharmacovigilance.
Results Of the 122 students in the class, the response rate was 95.90% (n=117). The work group helped to better explain to the students the reporting circuit, however 28 participants reported their inability to report ADR in their future practice (25.92%). Regarding the obligation to report ADRs, 99.4% of students (n=116) thought that it should be made legally valid for all health professionals. The same number (n=116) found the role of pharmacovigilance to be important. In addition, almost all of the comments collected after the tutorials reflected students' appreciation of this initiative and their desire to receive more sessions.
Conclusion In this study, students expressed the desire to learn more about pharmacovigilance during their university education. This result led to the introduction of a system of pharmacovigilance work groups for third- and fourth-year pharmacy students for the 2018–2019 academic year.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Thanks to all participants.
No conflict of interest.

6ER-024 ASPIRIN COMPARED TO ENOXAPARIN OR RIVAROXABAN FOR THE PREVENTION OF VTE FOLLOWING HIP AND KNEE REPLACEMENT – A RETROSPECTIVE COHORT STUDY IN IRELAND

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Background The risk of venous VTE following major orthopaedic surgery is among the highest for all surgical specialties, and can result in significant morbidity and mortality. Guidelines for thromboprophylaxis following elective primary total hip or knee replacement (THR or TKR) in the Cappagh National Orthopaedic Hospital (CNOH) are based on American College of Chest Physicians (ACCP) guidance. The most recent change to local guidelines was the introduction of the extended aspirin regimen as standard thromboprophylaxis.
Purpose The aim of this study was to establish the effectiveness of this regimen by comparing VTE rates in patients receiving extended aspirin to those receiving inpatient enoxaparin or modified rivaroxaban regimens.
Methods This was a retrospective cohort study. Data were collected from the CNOH patient record software. All eligible patients who underwent primary TKR or THR between 1 January 2010 and 30 June 2016 were included (n=6,548).
Results The overall VTE rate was 0.99%. The VTE rate in both the inpatient enoxaparin group (n=961) and extended aspirin group (n=3,460) was 1.04%. The VTE rate in the modified rivaroxaban group (n=1,212) was lower at 0.66%, but the difference was not statistically significant (p=0.154). A history of VTE was the only significant demographic risk factor for post-operative VTE (0.87% vs. 3.54%, p=0.0002).
Conclusion These findings confirm the effectiveness of our current standard thromboprophylaxis regimen. The results are generalisable to patients undergoing elective primary THR or TKR nationally and internationally. This study adds to the growing evidence supporting the use of aspirin thromboprophylaxis in the orthopaedic setting.

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6ER-025 IMPACT OF THE NEW EUROPEAN REGULATION ON CLINICAL TRIALS IN THE ACTIVITY AND DYNAMICS OF RESEARCH ETHICS COMMITTEES FROM CATALONIA

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Background Clinical research proposals on humans as clinical trials (CT), post-authorisation studies or any project must be submitted to an independent research ethics committee (REC). Different legislation has regulated CT in Spain, the last two European transpositions significantly modified the dynamics of REC, especially the most recent one, currently in force. Spain was the first European country to apply Regulation (EU) No 536/2014 with publication in December 2015 of Royal Decree 1090/2015.
Purpose The objective was to analyse and quantify the impact of Regulation (EU) No 536/2014 on the dynamics and activity of RECs from Catalonia regarding CT evaluation.
Material and methods Through an official request to the Catalonian Health Service, annual activity reports that RECs from Catalonia have to present to competent government agency, were analysed.

Two periods were established: period 2007–2015 (under Directive 2001/20/CE) and period 2016 (under Regulation No 536/2014).

RECs were classified into three groups: high (Group 1), medium (Group 2) and low (Group 3), according to their annual evaluation activity.

Meetings number and evaluation activity were recorded. Descriptive statistical analysis was performed using SPSS.v.19. No normal distribution was resulted (Kolmogorov–Smirnov test), so the Mann–Whitney *U* test was used, statistical significance p<0.05.
Results Three-hundred and seventy-four reports from 47 RECs were reviewed. The median number of meetings per period, analysed by type of REC were:

Abstract 6ER-025 Table 1

	PERIOD 1	PERIOD 2	p
GROUP 1:	22 (IQR=11)	47 (IQR=25)	0.117
GROUP 2:	22 (IQR=10)	16.5 (IQR=14.7)	0.469
GROUP 3:	10 (IQR=12)	8.5 (IQR=11.2)	0.232

p=0.227 (period 1 vs. period 2, globally)