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Impact of the New Regulation of Clinical Trials: A First View of Research Ethics Committees from Catalonia (Spain)

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Abstract: The introduction of Regulation (EU) No. 536/2014, enacted in Spain through Royal Decree 1090/2015, transformed the ethics review landscape governing clinical trials. As one of the first regions to implement these reforms, Catalonia's Research Ethics Committees (RECs) have experienced notable shifts—both positive and challenging—in how they operate and evaluate studies. This article reviews quantitative and qualitative effects observed in Catalonia's RECs, including activity metrics, administrative burden, and member satisfaction, providing a first comprehensive assessment of the consequences of regulatory change.

Keywords: Clinical trial regulation, Research Ethics Committees (RECs), Regulation (EU) No. 536/2014, Royal Decree 1090/2015 (Spain), Ethics.

INTRODUCTION

Clinical research is essential for advancing medical knowledge and patient care, but it must be conducted within a rigorous ethical framework. In Spain, a dynamic regulatory environment culminated in the application of Regulation (EU) No. 536/2014 via Royal Decree 1090/2015, which brought sweeping changes to the ethical review process for clinical trials[1][2][3]. Catalonia—the region with the highest number of RECs in Spain—serves as an informative model to assess the initial impact of this regulation[4][5].

BACKGROUND: THE NEW REGULATORY LANDSCAPE

- **Regulation (EU) No. 536/2014:** Streamlines procedures, harmonizes assessments across Europe, emphasizes participant safety, and mandates greater transparency in trial reporting.
- **Royal Decree 1090/2015:** Spanish implementation, introduces a single National Ethics Committee opinion (replacing review by each participating site's committee), strengthens REC credentials, and requires the inclusion of at least one patient or layperson per REC[1][2][3][6].
- **Key Innovations:**
    - Single REC opinion valid nationwide

- Coordinated review between REC and the Spanish Agency of Medicines and Medical Devices (AEMPS)
- Standardized composition and accreditation of RECs[3][6]

METHODS

A mixed-methods analysis was conducted drawing on surveys and annual activity reports from 31 accredited Catalan RECs before and after the regulatory shift. Quantitative activity metrics (committee meetings, number of trials evaluated) and member satisfaction scores were assessed. Data were analyzed using descriptive statistics, non-parametric tests, and qualitative review of open-ended responses[4][5].

RESULTS

Activity Metrics: A Quantitative Perspective

Metric	Pre-Regulation	Post-Regulation	Statistical Significance
Number of committee meetings	No significant change	No significant change	$p = 0.329$ [5]
Number of clinical trials evaluated	Stable or increasing	Sharp decrease	$p < 0.001$ [5]

Key findings:

- The number of REC meetings held annually remained stable.
- **A sharp decline in the number of clinical trial evaluations** was observed in the period following regulatory implementation, despite minor fluctuations in previous years[4][5].

Table: Impact on REC Activity and Member Satisfaction

Indicator	Before Regulation	After Regulation
Satisfaction Score (Median, 0–10)	8 (IQR: 3)	6 (IQR: 3)
Number of CTs evaluated (per year)	Higher	Marked reduction

Graph: Annual Number of Clinical Trials Evaluated by Catalan RECs

Year	Number of Trials Evaluated
Pre-2016	Increasing or stable trend
Post-2016	Pronounced decrease

(The above reflects available quantitative observations on the Catalan REC system[4][5].)

Member and Committee Satisfaction

- **Satisfaction before regulation (median):** 8/10
- **Satisfaction after regulation (median):** 6/10
- **Major determinants of dissatisfaction:**
  - Increased administrative burden for local RECs
  - Marginalization of site-specific ethical concerns
  - Perceived loss of influence over trial approval for local investigators

Despite reductions in evaluative variability and faster national approvals, a majority of REC members report a less favorable experience under the new system[4][1].

DISCUSSION

Positive Impacts

- **Harmonization and Consistency:** The new regulation reduced variability in REC evaluation outcomes, ensuring that multicenter trials receive more uniform ethical scrutiny[1][2].

- **Administrative Efficiency:** Centralized reviews via a single accredited REC expedited the overall approval process[1][3].
- **Increased Transparency:** Mandated registration and reporting requirements enhance public trust in clinical research[3][6].

Challenges and Concerns

- **Reduced REC Involvement:** Local RECs report feeling sidelined in trial oversight, raising concerns about insufficient consideration of local context and hospital-specific factors[4][5].
- **Satisfaction Decline:** The new procedure, while administratively streamlined, has reduced member satisfaction—potentially due to decreased active participation and perceived fragmentation of ethical oversight[4][5].
- **Learning Curve and Remodelling:** Significant remodelling of committee functions required new standard operating procedures, retraining, and workflow realignment, imposing a transitional burden on personnel[4][5].

Qualitative Perspectives

- While the benefits of standardization and speed are recognized, doubts and negative elements (e.g., administrative overload, lack of responsiveness to local needs) currently predominate among committee members in Catalonia[4][5].

CONCLUSION

Spain's pioneering early adoption of the new European regulation on clinical trials—viewed through the lens of Catalan Research Ethics Committees—offers instructive lessons for harmonizing ethical oversight while maintaining local accountability. Early data from Catalonia reveal **administrative efficiencies but at a cost of reduced REC activity and lower satisfaction among committee members**. Continuous evaluation and potential adjustment are warranted to balance centralized efficiency with the expertise and contextual sensitivity local RECs provide[4][5][1].

Table 1. REC Activity and Satisfaction Pre- and Post-Regulation

Metric	Pre-Regulation	Post-Regulation	Change
REC meetings	Unchanged	Unchanged	None
Trials evaluated	Stable/increasing	Sharp decrease	Marked reduction
Satisfaction (median)	8/10	6/10	Significant decrease

Recommendations

- Mechanisms for local REC input should be retained or strengthened to ensure contextual relevance without sacrificing the benefits of centralization.
- Ongoing training and adaptation support for REC members are crucial to facilitate the transition.
- Further research is needed to assess patient perspectives, long-term trends, and possible adjustments to the regulatory framework.

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