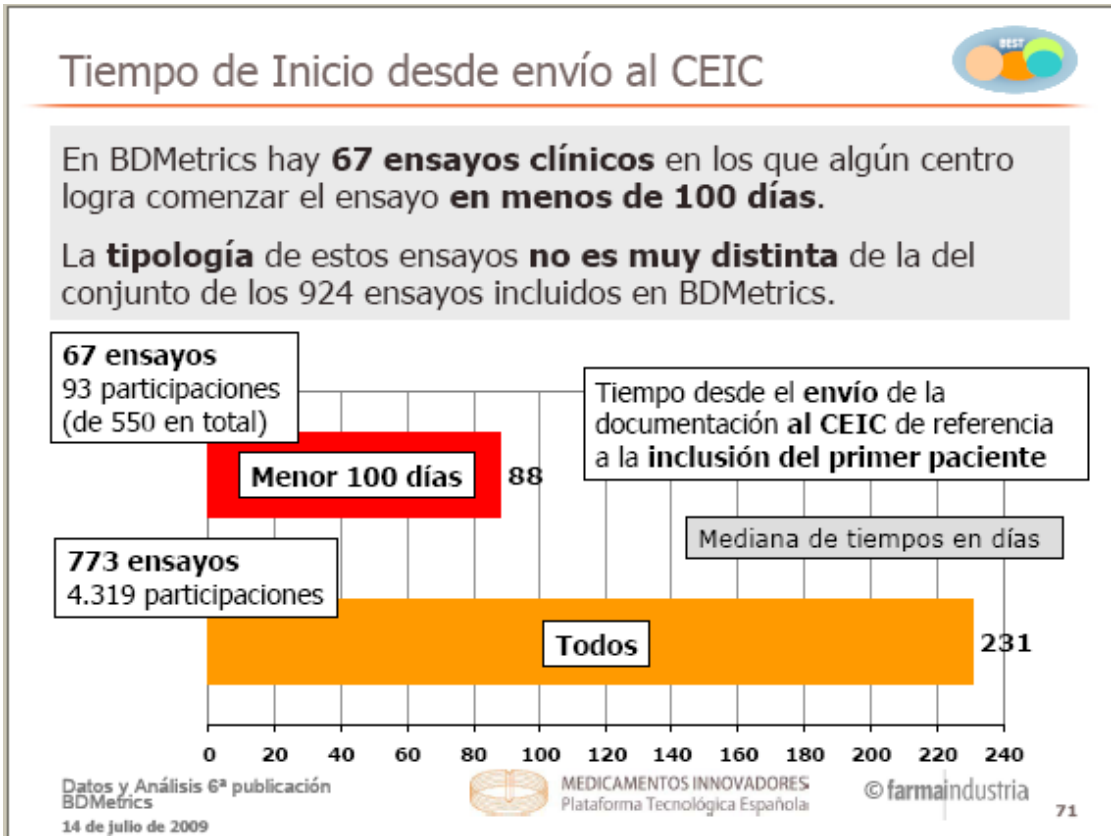
Information provided by Farmaindustria (Spain) in relation to the delays mentioned under Section 3.2 Weaknesses of the Consultation Paper on the Functioning of the Clinical Trials Directive

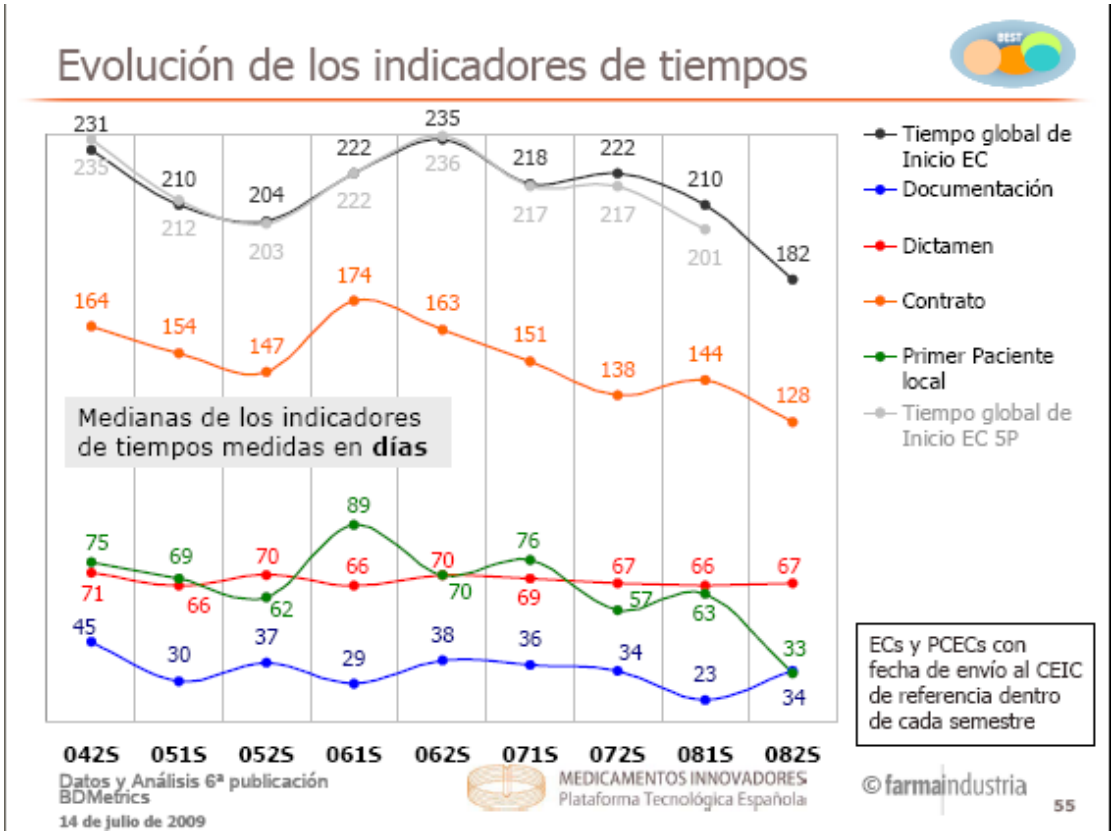
The time period from the submission of protocol to the first-patient in: 231 days. Nevertheless, in 67 clinical trials out of 773, the median of the first-patient is 88 days



The time of assessment of the request of a clinical trial from Ethics Committee and ME are in line with the Directive (67 days).

……

In Spain, the need to sign an agreement with each of the Centres' participants in the study, significantly delays the start of the study. There is no legal timeframe for signatures of these kind of agreements. From the submission of the clinical trial to the Ethics Committee until finally obtaining the agreement from the Centre takes a median of 128 days.

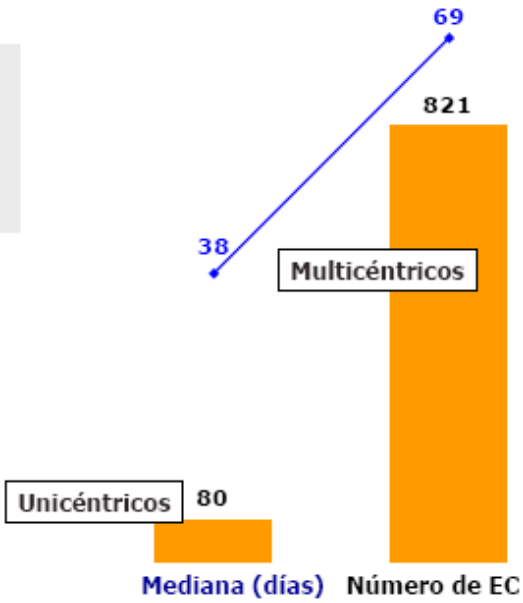


Phase I trials can be started before other types of studies, this is probably due to the fact that this studies are normally unicentric ones and the assessment from the Ethic Committee is faster than in multicentric ones (median of 38 days for unicentric vs 69 days for multicentric; median of 45 days for phase Ia studies vs 56 days for phase Ib vs 67 for phase II studies)

Etapa Dictamen

Influencia del número de centros que participan en el ensayo

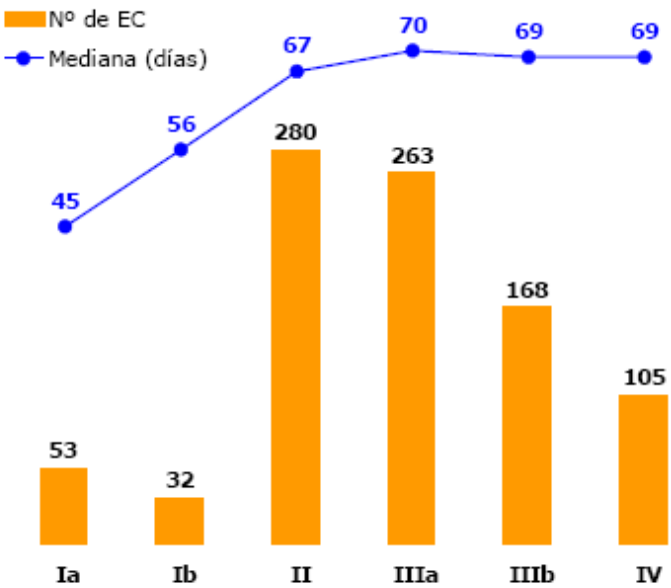
En los **EC unicéntricos se tarda 31 días menos** en emitir el dictamen

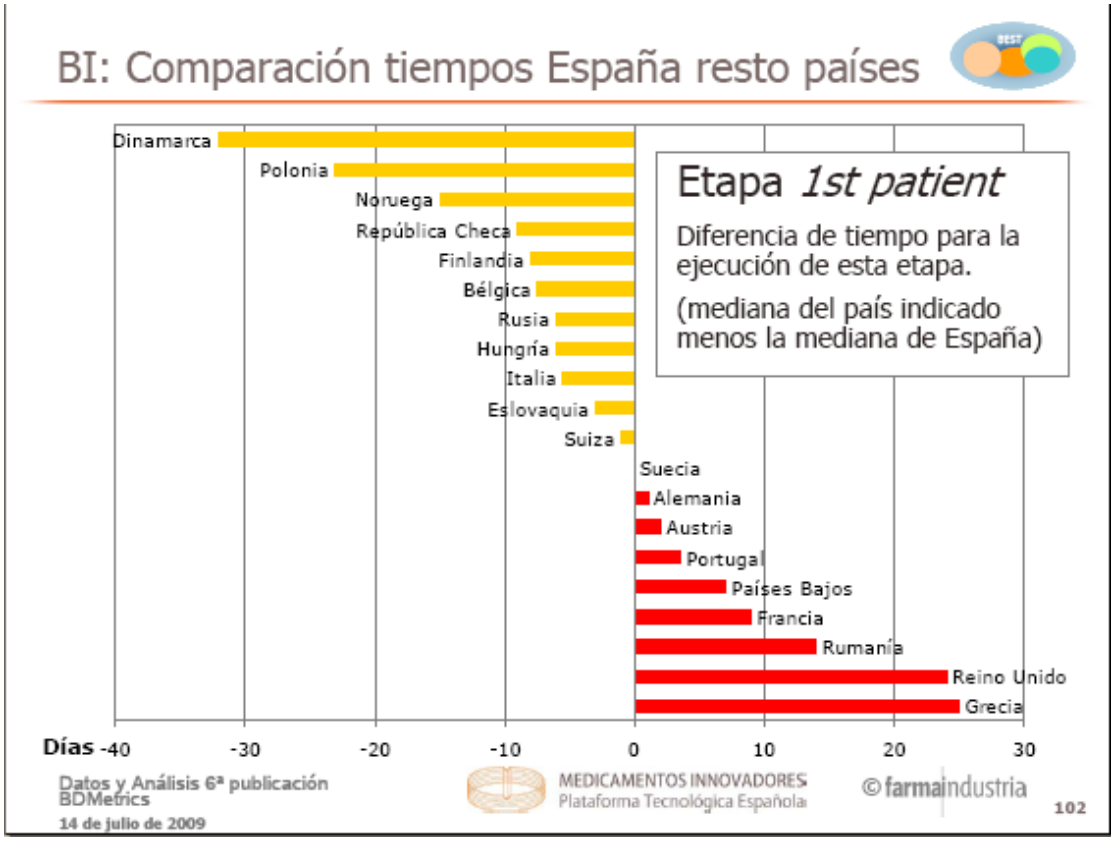


Etapa Dictamen

Influencia de la fase de la investigación

En los EC en **fases Ia y Ib** el CEIC **tarda menos** en emitir el dictamen





This chart shows the differences between EU countries in time for “first patient in”