



Criterios de excelencia para la realización de ensayos clínicos

Atracción de fases tempranas

Dra. Valentina Boni, MD PhD

Medical Oncologist, Principal Investigator
Molecular Tumor Board Coordinator

START Madrid Early Phase Program
Centro Integral Oncológico Clara Campal
Hospital de Madrid, Sanchinarro



Un caso de éxito:

Paciente de 45 años de edad diagnosticado en Septiembre del 2013 de cáncer microcitico de pulmón estadio IV

Visto en nuestra Unidad por primera vez en Mayo 2015, PD a 2 líneas de tto estándar

Inicia en Junio 2015 EC de fase 1/2 con Nivolumab

Actualmente sigue en tto con perfecto estado general y se fue a viajar!



Key objectives in early phase trials:

- Early access to New anti cancer therapies
- Effectiveness, Safety and less Toxicities in comparison to conventional treatment
- To accelerate the development of new anticancer therapies for the cure of cancer

Critical challenges in early drug development:

- New trial designs: adaptive, basket, platform trials etc.
- Complicated criteria and protocols
- Even more molecular
- Testing similar drugs... high competition in the same indication!

**High complexity and
cost...BUT**



PHASE 1 Unit: Key characteristics

- High-quality uniformed systems (SOPs, eMR)
- Quick contracts
- Fast IRB (every 2 weeks, for Ph1 studies)
- Staff
 - ▣ Highly qualified, specialized, trained
 - ▣ Full time
- “Know how”: organization, structures, technical knowledge
- Collaboration with community (patients, Oncologists)

Phase 1 Unit: Key characteristics

- Fast Data Entry and Remote Access
- Best Management of PK and PD samples
- Multidisciplinary Boards
- Comprehensive Architecture in Tumor-centered Programs



Valentina.boni@startmadrid.com