Registro FADOI-START

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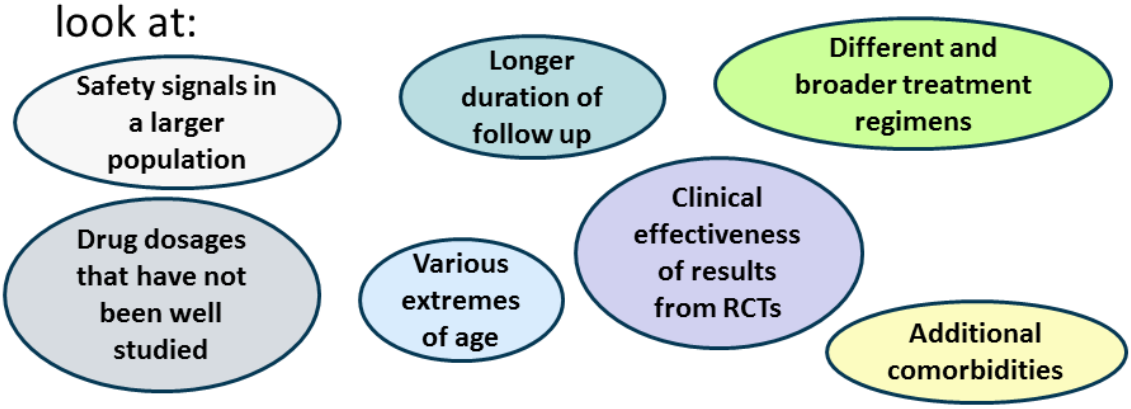
Randomized Controlled Trials and Real-World Data: How Do They Differ?

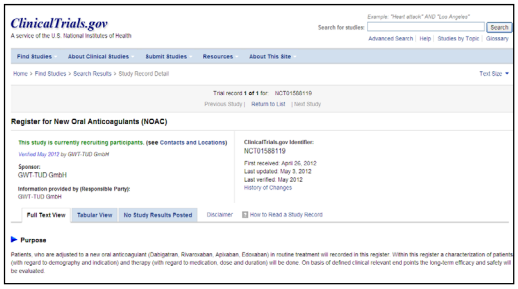
- RCTs test the efficacy of a drug in ideal circumstances with strict inclusion/exclusion criteria
- Real world data complements RCTs by allowing us to look at:



Hannan EL.. *J Am Coll Cardiol Intv.* 2008;1:211-217.
Sørensen HT. *Hepatology.* 2006;1075-1082.

Real-life data AF

Dresden NOAC Registry



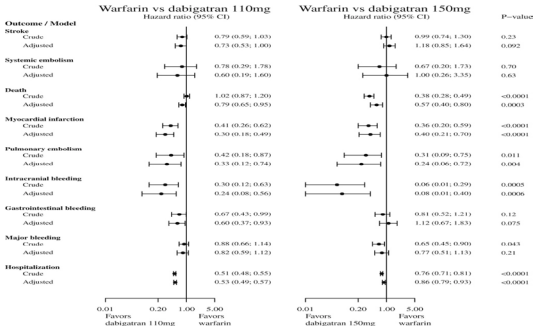
Mini Sentinel (FDA)

Intracranial and Gastrointestinal Bleeding Events in New Users of Dabigatran and Warfarin from the Mini-Sentinel Distributed Database, October 2010 through December 2011.*

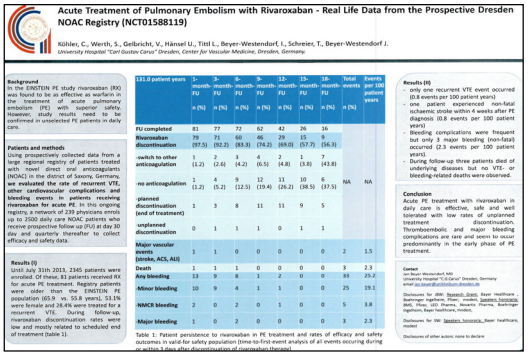
Analysis	Dabigatran			Warfarin		
	No. of Patients	No. of Events	Incidence no. of events/ 100,000 days at risk	No. of Patients	No. of Events	Incidence no. of events/ 100,000 days at risk
Gastrointestinal hemorrhage						
Analysis with required diagnosis of atrial fibrillation	10,599	16	1.6	43,541	160	3.5
Sensitivity analysis without required diagnosis of atrial fibrillation	12,195	19	1.6	119,940	338	3.1
Intracranial hemorrhage						
Analysis with required diagnosis of atrial fibrillation	10,587	8	0.8	43,594	109	2.4
Sensitivity analysis without required diagnosis of atrial fibrillation	12,182	10	0.9	120,020	204	1.9

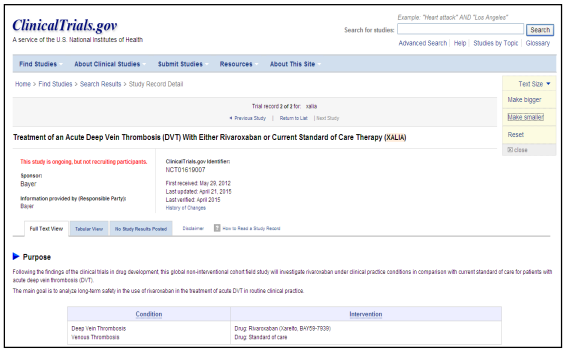
Gloria AF registry

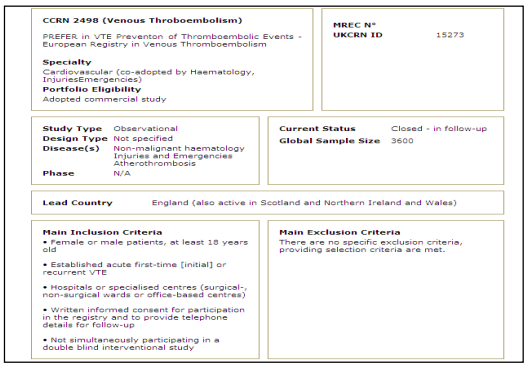
Danish Registry



Real-life data VTE







Post-authorization Studies

- Post-marketing surveillance studies (PMSS)
- Non-interventional studies
- Registries

In Italia?

START-Register

http://www.start-register.org

Perchè un altro registro?

- 300 Reparti di Medicina Interna (o Geriatria) in tutta Italia

- 2700 Soci (40% under 40)

Obiettivi

- Raccogliere Informazioni Real World sull'efficacia e la sicurezza dei DOACs nei pazienti con Trombosi Venosa Profonda ed Embolia Polmonare in gruppi di pazienti poco rappresentati negli studi di fase III e negli studi post marketing

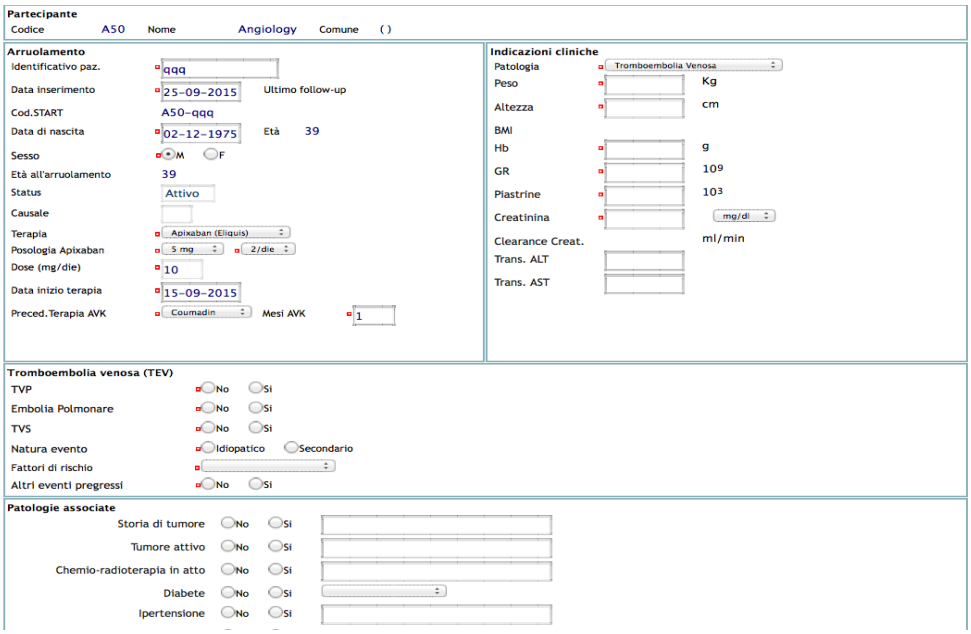
- Migliorare la gestione di questi pazienti (scopo educazionale societario)

START - Register

SURVEY ON ANTICOAGULATED PATIENTS - REGISTER

Registro computerizzato per la raccolta di dati di pazienti trattati cronicamente con anticoagulanti

FADOI

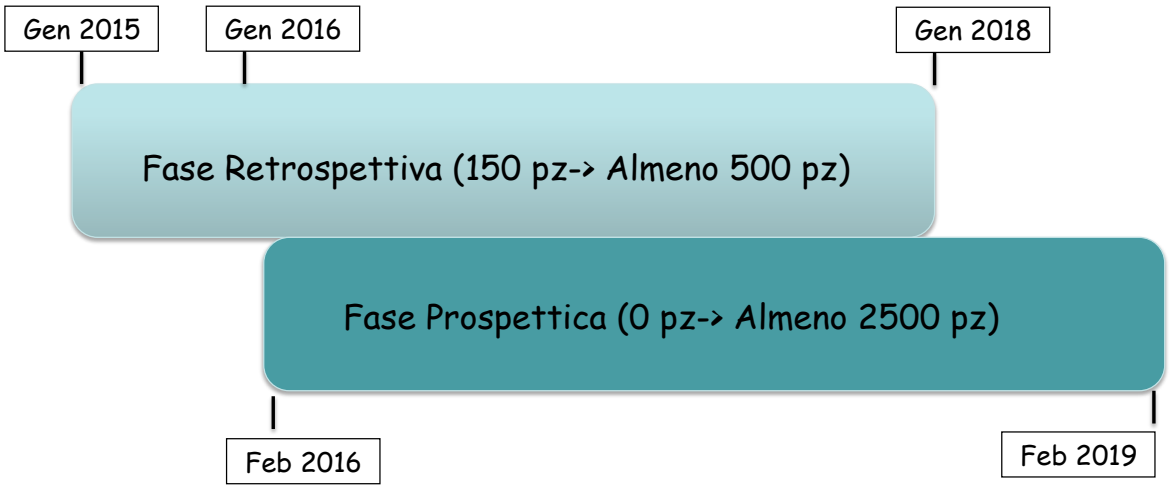


Registro FADOI/START

- Pazienti con TEV (TVP/EP)
- Trattati con DOAC
- Retrospettivo/prospettico
- Referenti regionali
- Coordinamento Centro Studi FADOI

Farmaci	DOACs
Indicazione	Solo TVP (anche arti superiori) e EP, NO Fibrillazione Atriale, TEV sedi atipiche, TVS
Setting	Ospedaliero/Ambulatoriale, prevalentemente ospedaliero per le EP
Durata del follow up	Max 3 anni. Fino a terapia attiva più 3 mesi dal termine della terapia
Visite di follow up	Libere, minimo 2 all'anno

Timeline



Grazie per l'attenzione!!!