



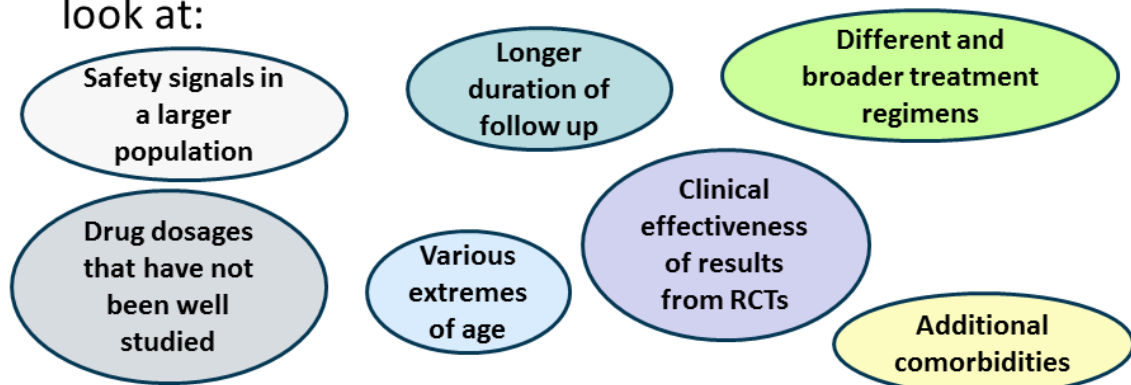
## Registro FADOI-START

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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 Interv.* 2008;1:211-217.  
Sørensen HT. *Hepatology.* 2006;1075-1082.

# Real-life data AF

## Dresden NOAC Registry

**ClinicalTrials.gov**  
A service of the U.S. National Institutes of Health

Example: "Heart attack" AND "Los Angeles" Search

Advanced Search | Help | Studies by Topic | Glossary

Home > Find Studies > Search Results > Study Record Detail

The record ID is for: NCT01588119  
Phase 3 Study | Status: Not Yet Recruiting

**Register for New Oral Anticoagulants (NOAC)**

This study is currently recruiting participants. (see contacts and locations)

**Sponsor:** GWIT TUD GmbH

**Information provided by (Responsible Party):** GWIT TUD GmbH

**Full Text View | Tabular View | No Study Results Posted**

**Purpose:** Patients, who are adjusted to a new oral anticoagulant (Dabigatran, Rivaroxaban, Apixaban, Edoxaban) in routine treatment will be recruited in this register. Within this register a characterization of patients (with regard to comorbidity and medication) and therapy with regard to medication, dose and duration will be done. On basis of defined clinical relevant end points the long-term efficacy and safety will be evaluated.

## 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
<b>Gastrointestinal hemorrhage</b>						
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
<b>Intracranial hemorrhage</b>						
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

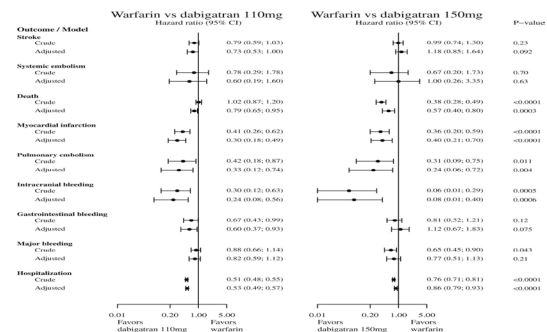
### Results of the 1st Phase of the International GLORIA-AF Registry Program: Regional Treatment Differences Before the Era of Novel Anticoagulants

MV Huismans, CS Ma, HC Diener, SJ Dubner, JL Halperin, KJ Rothman, C Teutsch, A Clemens, K Zint, E Kleine, DB Bartels, **GUYH Lip** for the GLORIA-AF Investigators



Global Registry on Long-Term Oral Antithrombotic Treatment in Patients with Atrial Fibrillation

## Danish Registry



# Real-life data VTE

**Acute Treatment of Pulmonary Embolism with Rivaroxaban - Real Life Data from the Prospective Dresden NOAC Registry (NCT01588119)**

Röckle, C., Werth, S., Dellmann, V., Havelik, T., Till, L., Beyer-Westendorf, J., Schneider, T., Beyer-Westendorf, J., University Hospital "Carl Gustav Carus" Dresden, Center for Vascular Medicine, Dresden, Germany

**Background:** In the EINSTEIN PE study rivaroxaban (RO) was found to be as effective as warfarin in the treatment of acute pulmonary embolism (PE) with equivalent safety. However, study results need to be confirmed in unselected PE patients in daily practice.

**Patients and methods:** Long prospectively collected data from a large regional registry of patients treated with novel direct oral anticoagulants (NOAC) in the district of Saxony, Germany, we evaluated the rate of recurrent VTE, other cardiovascular complications and bleeding events in patients treated with RO. In this registry, a network of 133 physicians across all 2008 daily care NOAC centers who receive prospective follow-up (FU) at day 30 day and monthly thereafter to collect efficacy and safety data.

**Results (N=113):** 113 patients were included. 53 patients received RO. 60 patients received FU. 11 patients were lost to follow-up. 11 patients were lost to follow-up. 11 patients were lost to follow-up.

113 PE patients	RO	Warfarin	no anticoagulation	RO	Warfarin	no anticoagulation	RO	Warfarin	no anticoagulation	RO	Warfarin	no anticoagulation	RO	Warfarin	no anticoagulation	RO	Warfarin	no anticoagulation
RO completed	81	77	72	62	42	26	36											
RO discontinued	29	71	68	48	28	12	5											
switch to other anticoagulation	1	2	8	4	2	1	9											
unselected discontinuation	1	4	8	12	10	6	NA											
RO completed	12	12	12	12	12	12	12											
RO discontinued	1	3	8	11	11	9	5											
switch to other anticoagulation	1	1	1	1	1	1	1											
unselected discontinuation	1	1	1	1	1	1	1											
Major vascular events (stroke, ACS, AHA)	1	1	0	0	0	0	2	1.5										
Death	1	1	1	0	0	0	3	2.3										
Any bleeding	11	9	4	1	2	0	88	25.2										
Minor bleeding	10	9	4	1	1	0	25	19.1										
Major bleeding	2	0	2	0	1	0	5	3.8										
MI/CS bleeding	1	0	2	0	0	0	3	2.3										

**ClinicalTrials.gov**  
A service of the U.S. National Institutes of Health

Example: "Heart attack" AND "Los Angeles" Search

Advanced Search | Help | Studies by Topic | Glossary

Home > Find Studies > Search Results > Study Record Detail

The record ID is for: NCT01600007

**Treatment of an Acute Deep Vein Thrombosis (DVT) With Either Rivaroxaban or Current Standard of Care Therapy (KALIA)**

This study is ongoing, but not recruiting participants.

**Sponsor:** Bayer

**Information provided by (Responsible Party):** Bayer

**Purpose:** Following the findings of the clinical trials in drug development this global non-interventional cohort field study will investigate rivaroxaban under clinical practice conditions in comparison with current standard of care for patients with acute deep vein thrombosis (DVT). The main goal is to analyze long-term safety in the use of rivaroxaban in the treatment of acute DVT in routine clinical practice.

Condition	Intervention
Deep Vein Thrombosis	Drug: Rivaroxaban (bayer), BAY189076
Venous Thrombosis	Drug: Standard of Care

**CCRN 2498 (Venous Thromboembolism)**

PREFER in VTE Prevention of Thromboembolic Events - European Registry in Venous Thromboembolism

**Specialty:** Cardiovascular (co-adopted by Haematology, Intensive Care Medicine)

**Portfolio Eligibility:** Adopted commercial study

**Study Type:** Observational

**Design Type:** Not specified

**Disease(s):** Non-malignant haematology disorders and thromboembolism

**Phase:** N/A

**Lead Country:** England (also active in Scotland and Northern Ireland and Wales)

**Main Inclusion Criteria:** Female or male patients, at least 18 years old

**Main Exclusion Criteria:** There are no specific exclusion criteria, providing selection criteria are met.

**Current Status:** Closed - in follow-up

**Global Sample Size:** 3600

**Established acute first-time (initial) or recurrent VTE**

- Hospital or specialised centres (surgical, non-surgical wards or office-based centres)
- Written informed consent for participation in the registry and to provide telephone details for follow-up
- Not simultaneously participating in a double blind interventional study

**Garfield**  
global anticoagulant registry in the field

# Post-authorization Studies

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



In Italia?

# START-Register

<http://www.start-register.org>

**START - Register**  
**SURVEY ON ANTICOAGULATED PATIENTS - REGISTER**  
Registro computerizzato per la raccolta di dati di pazienti trattati cronicamente con anticoagulanti

Home Area riservata partecipanti Chi siamo Contatti **Partecipa al registro**

**START-SSC**

### Il Registro START

**Razionale**  
La terapia anticoagulante orale con farmaci antagonisti della vitamina K (TAO) è la terapia d'elezione per la tromboprofilassi di alcune patologie largamente diffuse nella popolazione (fibrillazione atriale e tromboembolismo venoso). Altri farmaci anticoagulanti a somministrazione parenterale, quali le eparine a basso peso molecolare e il fondaparinux sono già utilizzati per un uso prolungato in alcune delle stesse indicazioni cliniche (ad es. tromboembolie venose)...

**Registro**  
Il Registro è unico e consentirà di raccogliere in modo standardizzato informazioni cliniche sull'impiego dei diversi farmaci anticoagulanti, sia quelli già disponibili sia quelli di prossima introduzione per l'uso clinico cronico. I pazienti arruolati potranno beneficiare di un monitoraggio clinico molto accurato, personalizzato e duraturo.

**Disegno**  
Registro prospettico multicentrico osservazionale. Ha lo scopo di contribuire al miglioramento dei trattamenti anticoagulanti mediante la raccolta dei dati di pazienti in trattamento anticoagulante cronico ad opera di centri o singoli professionisti dedicati al monitoraggio di

**Obiettivi e durata**  
Raccogliere prospetticamente mediante rete informatica informazioni sulla storia di pazienti trattati con farmaci anticoagulanti...

[leggi tutto](#)

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 educativo societario)



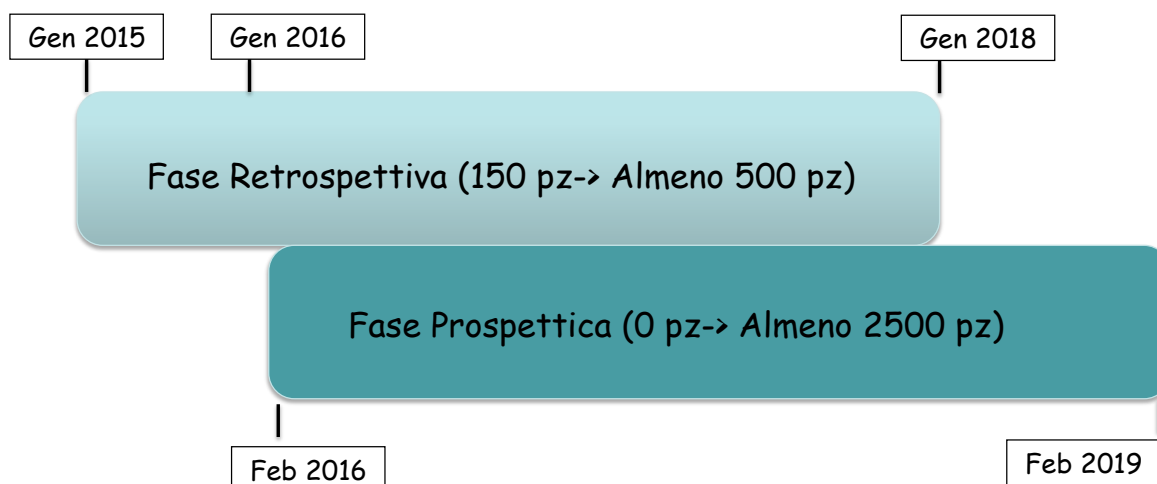
Partecipante		A50	Nome	Angiology	Comune	( )
<b>Arruolamento</b>						
Identificativo paz.	<input type="checkbox"/>	qqq				
Data inserimento	<input type="checkbox"/>	25-09-2015		Ultimo follow-up		
Cod.START	<input type="checkbox"/>	A50-qqq				
Data di nascita	<input type="checkbox"/>	02-12-1975		Età	39	
Sesso	<input checked="" type="radio"/>	M	<input type="radio"/>	F		
Età all'arruolamento	<input type="checkbox"/>	39				
Status	<input type="checkbox"/>	Attivo				
Causale	<input type="checkbox"/>					
Terapia	<input type="checkbox"/>	Apixaban (Eliquis)				
Posologia Apixaban	<input type="checkbox"/>	5 mg		2/die		
Dose (mg/die)	<input type="checkbox"/>	10				
Data inizio terapia	<input type="checkbox"/>	15-09-2015				
Preced.Terapia AVK	<input type="checkbox"/>	Coumadin		Mesi AVK	1	
<b>Indicazioni cliniche</b>						
Patologia	<input type="checkbox"/>	Tromboembolia Venosa				
Peso	<input type="checkbox"/>				Kg	
Altezza	<input type="checkbox"/>				cm	
BMI	<input type="checkbox"/>				g	
Hb	<input type="checkbox"/>				10 <sup>9</sup>	
GR	<input type="checkbox"/>				10 <sup>3</sup>	
Piastrine	<input type="checkbox"/>					
Creatinina	<input type="checkbox"/>				mg/dl	
Clearance Creat.	<input type="checkbox"/>				ml/min	
Trans. ALT	<input type="checkbox"/>					
Trans. AST	<input type="checkbox"/>					
<b>Tromboembolia venosa (TEV)</b>						
TVP	<input checked="" type="radio"/>	No	<input type="radio"/>	Si		
Embolia Polmonare	<input checked="" type="radio"/>	No	<input type="radio"/>	Si		
TVS	<input checked="" type="radio"/>	No	<input type="radio"/>	Si		
Natura evento	<input checked="" type="radio"/>	Idiopatico	<input type="radio"/>	Secondario		
Fattori di rischio	<input type="checkbox"/>					
Altri eventi progressi	<input checked="" type="radio"/>	No	<input type="radio"/>	Si		
<b>Patologie associate</b>						
Storia di tumore	<input type="radio"/>	No	<input type="radio"/>	Si		
Tumore attivo	<input type="radio"/>	No	<input type="radio"/>	Si		
Chemo-radioterapia in atto	<input type="radio"/>	No	<input type="radio"/>	Si		
Diabete	<input type="radio"/>	No	<input type="radio"/>	Si		
Iipertensione	<input type="radio"/>	No	<input type="radio"/>	Si		

## 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!!

