



# Genesis of National Registry of Interventional Cardiology From CRAC to France PCI

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## *Disclosure Statement of Financial Interest*

*I currently have, or have had over the last two years, an affiliation or financial interests or interests of any order with a company or I receive compensation or fees or research grants with a commercial company :*

Speaker's name: Grégoire, Range, Le Coudray

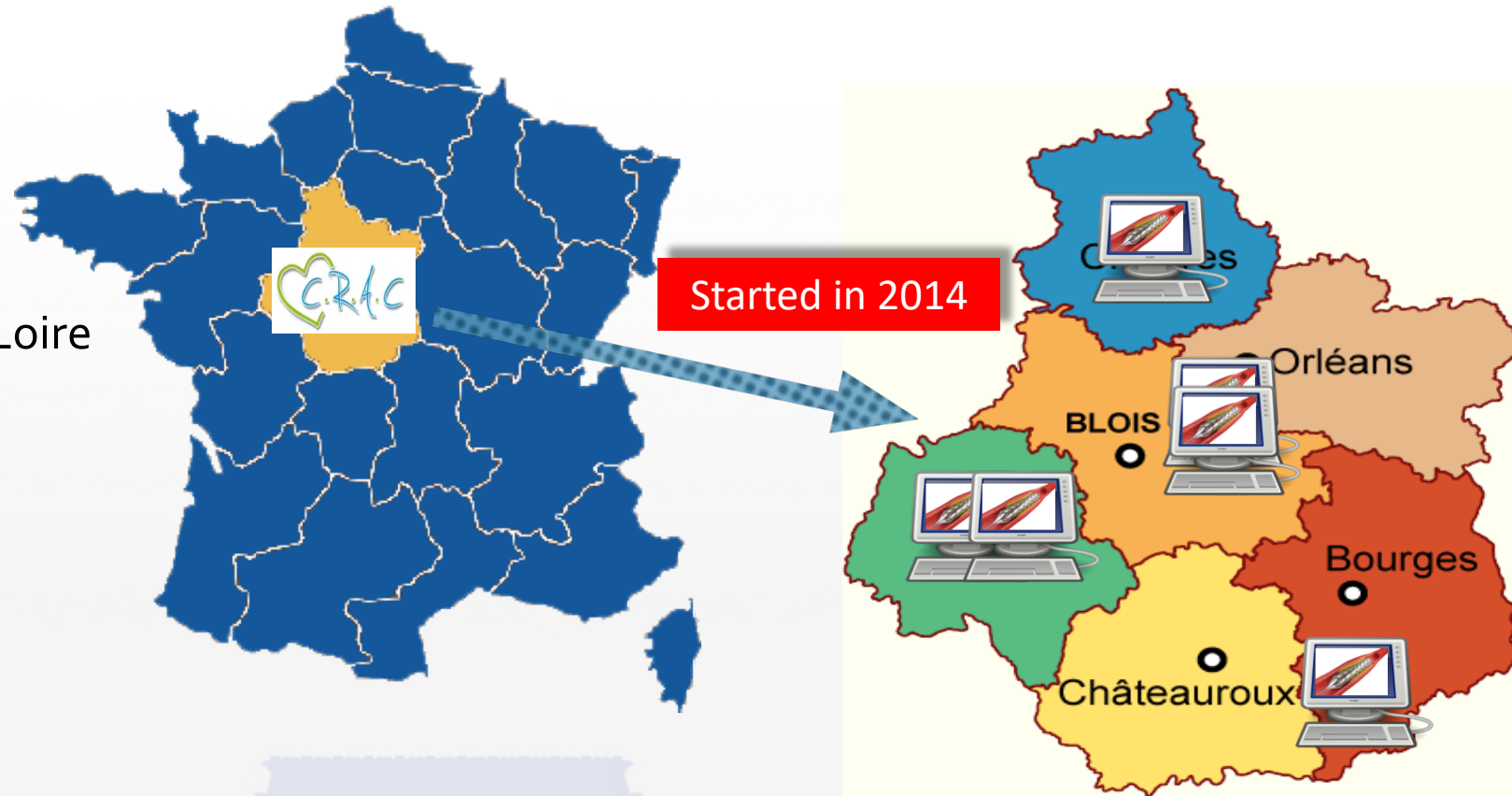
lien d'intérêt potentiel à déclarer :

Astra-Zeneca, Bayer, BMS, Biotronik, Abbott

# CRAC Registry

Club Régional des Angioplasticiens du Centre

- ✓ Région Centre Val de Loire
- ✓ 2,5 M of people
- ✓ 6 cath labs
- ✓ Annual Activity
  - ✓ 13000 procedures
  - ✓ 5000 PCI
  - ✓ 1000 STEMI < H24

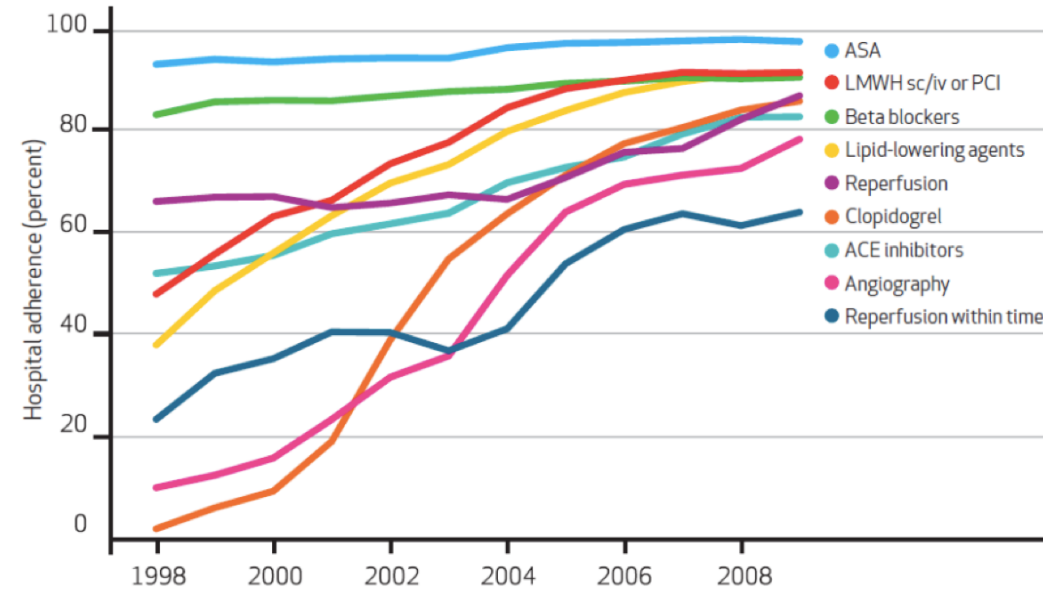


# Aim

## Improve medical practice



Hospitals' Adherence To Swedish National Guidelines For Treating Acute Myocardial Infarction, 1998-2009

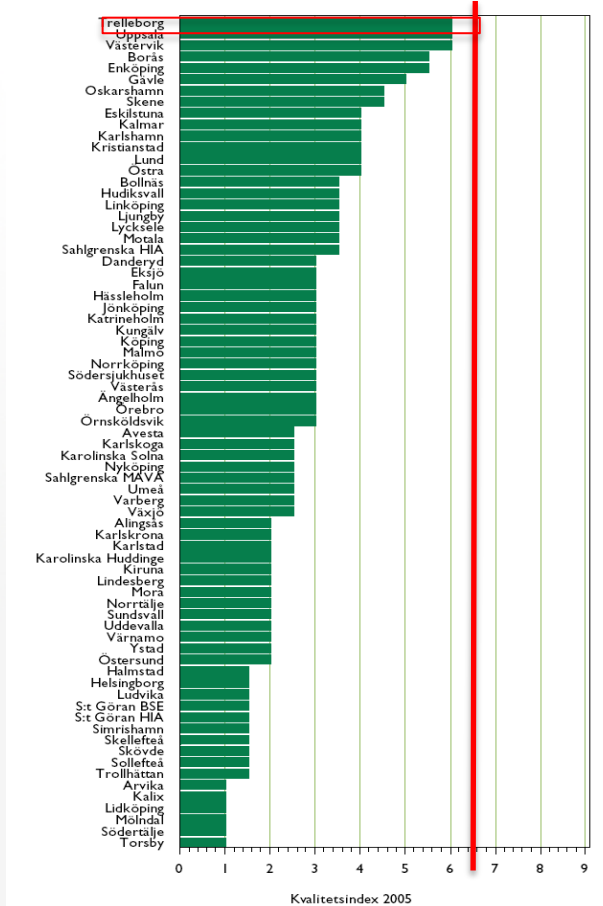




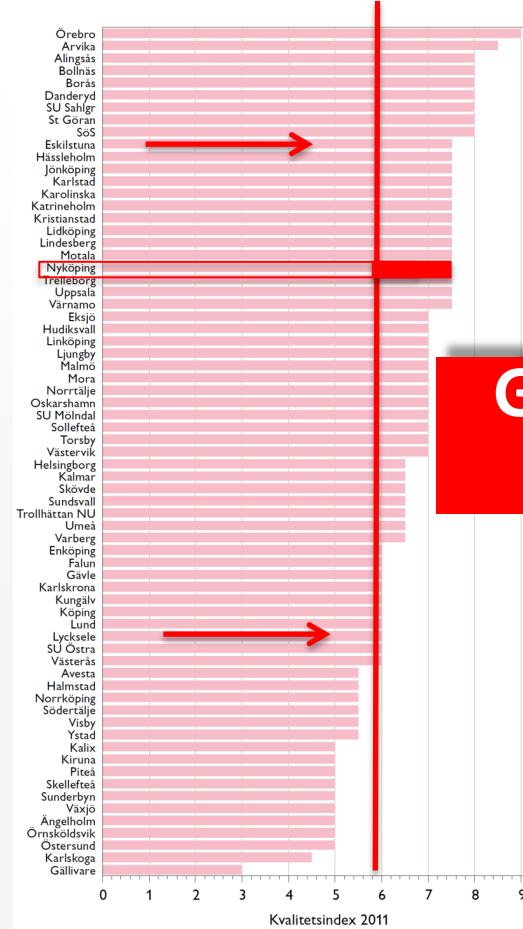
# Quality index in SwedenHeart



2005



2011



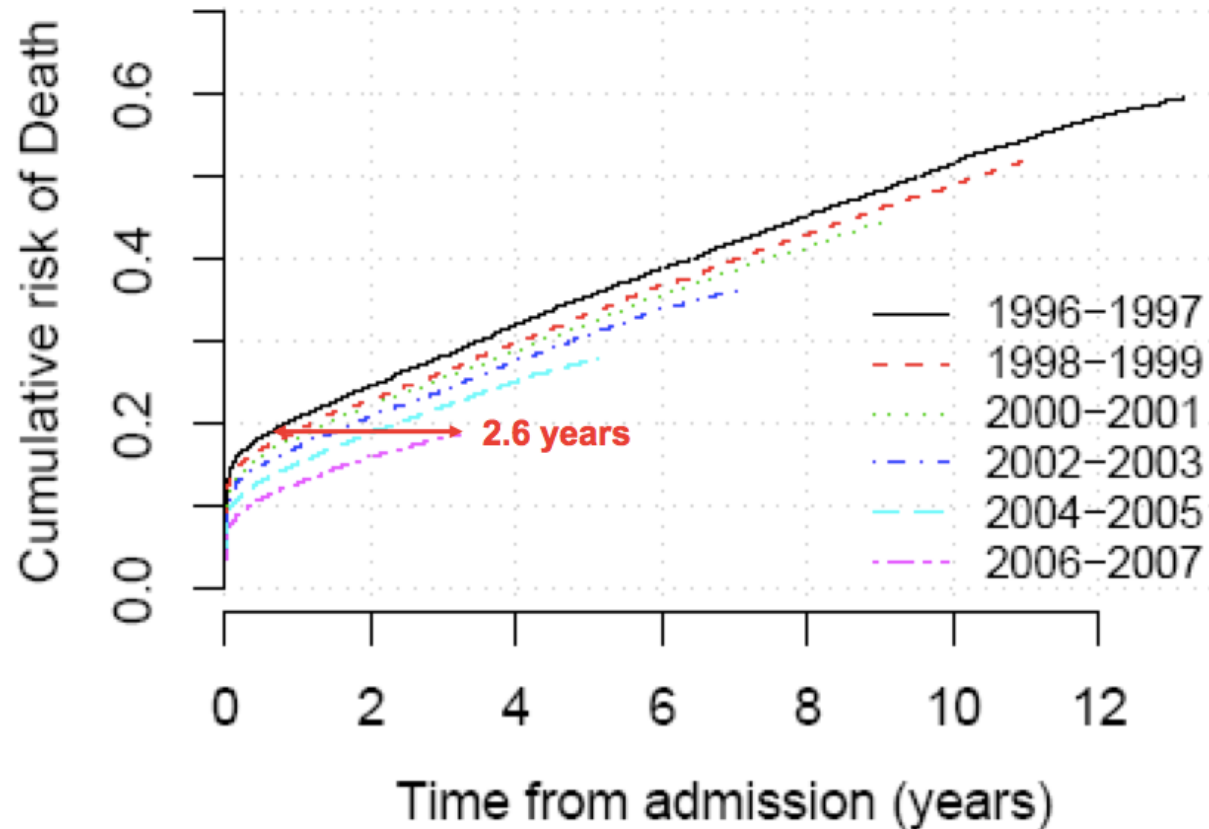
General improvement of quality of care

# Aim

## Improve prognosis of STEMI patient



### Long-term mortality in STEMI





# Aim

# Research/ Publications

## SWEDEHEART - Research

### Nationwide Cohort Study of Risk of Ischemic Heart Disease in Patients With Celiac Disease

Jonas F. Ludvigsson, MD, PhD; Stefan James, MD, PhD; Johan Askling, MD, PhD; Ulf Stenestrand, MD, PhD; Erik Ingelsson, MD, PhD

**Background**—Studies on ischemic heart disease (IHD) incidence in individuals with celiac disease (CD) are contradictory and do not take small intestinal pathology into account.  
**Methods and Results**—In this Swedish population-based cohort study, we examined the risk of IHD in patients with CD based on small intestinal histopathology. We defined IHD as death or incident disease in myocardial infarction or angina pectoris in Swedish national registers. In 2008 (Circulation. 2011;123:483-490.)  
Volume 123, Number 11, November 14, 2011

### Association Between Admission Supine Systolic Blood Pressure and 1-Year Mortality

Frank H. Nyström, MD, PhD  
**Objective** To study long-term mortality related to supine BP in patients admitted to the acute coronary care unit.  
**Design** JAMA. 2010;303(12):1167-1172

### Influence of Renal Function on the Effects of Early Revascularization in Non-ST-Elevation Myocardial Infarction

Data From the Swedish Web-System for Enhancement and Development of Evidence-Based Care in Heart Disease Evaluated According to Recommended Therapies (SWEDEHEART)

Kerstin Svanström, MD; Pia Lindman, MD, PhD; Stefan H. Jacobson, MD, PhD; Staffan Schön, MD; Johan Lindbäck, MSc; Ulf Stenestrand, MD, PhD; Lars Wallentin, MD, PhD; Tomas Jernberg

(Circulation. 2009;120:851-858.)

**Background**—It is unknown whether patients with

### The NEW ENGLAND JOURNAL of MEDICINE

ISSN 0096-9340 MAY 7, 2011

### Long-Term Safety and Efficacy of Drug-Eluting versus Bare-Metal Stents in Sweden

Stefan K. James, M.D., Ph.D., Ulf Stenestrand, M.D., PhD, Johan Lindbäck, MSc, Jörg Carlsson, M.D., Ph.D., Fredrik Schersten, M.D., Ph.D., Tage Nilsson, MD, Ph.D., Lars Wallentin, MD, Ph.D., and Bo Lagerqvist, MD, Ph.D., for the SCAAR Study Group\*

THE NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

### Long-Term Outcomes with Drug-Eluting Stents versus Bare-Metal Stents in Sweden

Bo Lagerqvist, M.D., Ph.D., Stefan K. James, M.D., Ph.D., Ulf Stenestrand, M.D., Ph.D., Johan Lindbäck, MSc, Tage Nilsson, M.D., Ph.D., and Lars Wallentin, M.D., Ph.D., for the SCAAR Study Group\*

### Long-term Outcome of Primary Percutaneous Coronary Intervention vs Prehospital

**40 high rank publications/year**

### Anticoagulation Therapy in Atrial Fibrillation in Combination With Acute Myocardial Infarction Influences Long-Term Outcome

A Prospective Cohort Study From the Register of Information and Knowledge About Swedish Heart Intensive Care Admissions (RIKS-HIA)

Ulf Stenestrand, MD, PhD; Johan Lindbäck, MSc; Lars V (Circulation. 2005;)

### Early revascularisation and 1-year survival in 14-day survivors of acute myocardial infarction: a prospective cohort study

Ulf Stenestrand, Lars Wallentin

#### Summary

**Background** Randomized trials of early revascularization in acute coronary syndromes have yielded conflicting results

#### Introduction

Results of randomized trials on the survival benefits of early revascularization after acute coronary syndromes are inconsistent. Lancet 2002; 359: 1805-11

### Association Between Adoption of Evidence-Based Treatment and Survival for Patients With ST-Elevation Myocardial Infarction

Tomas Jernberg, MD, PhD; Pia Johansson, MD, PhD; Claes Håk, MD, PhD

**Context** Only limited information is available on the speed of implementation of new evidence-based and guideline-based health care. JAMA. 2011;305(16):1677-1684

# STEMI Guidelines ESC 2017

It is recommended that all hospitals and EMS participating in the care of patients with STEMI record and audit delay times and work to achieve and maintain quality targets.<sup>105–107</sup>

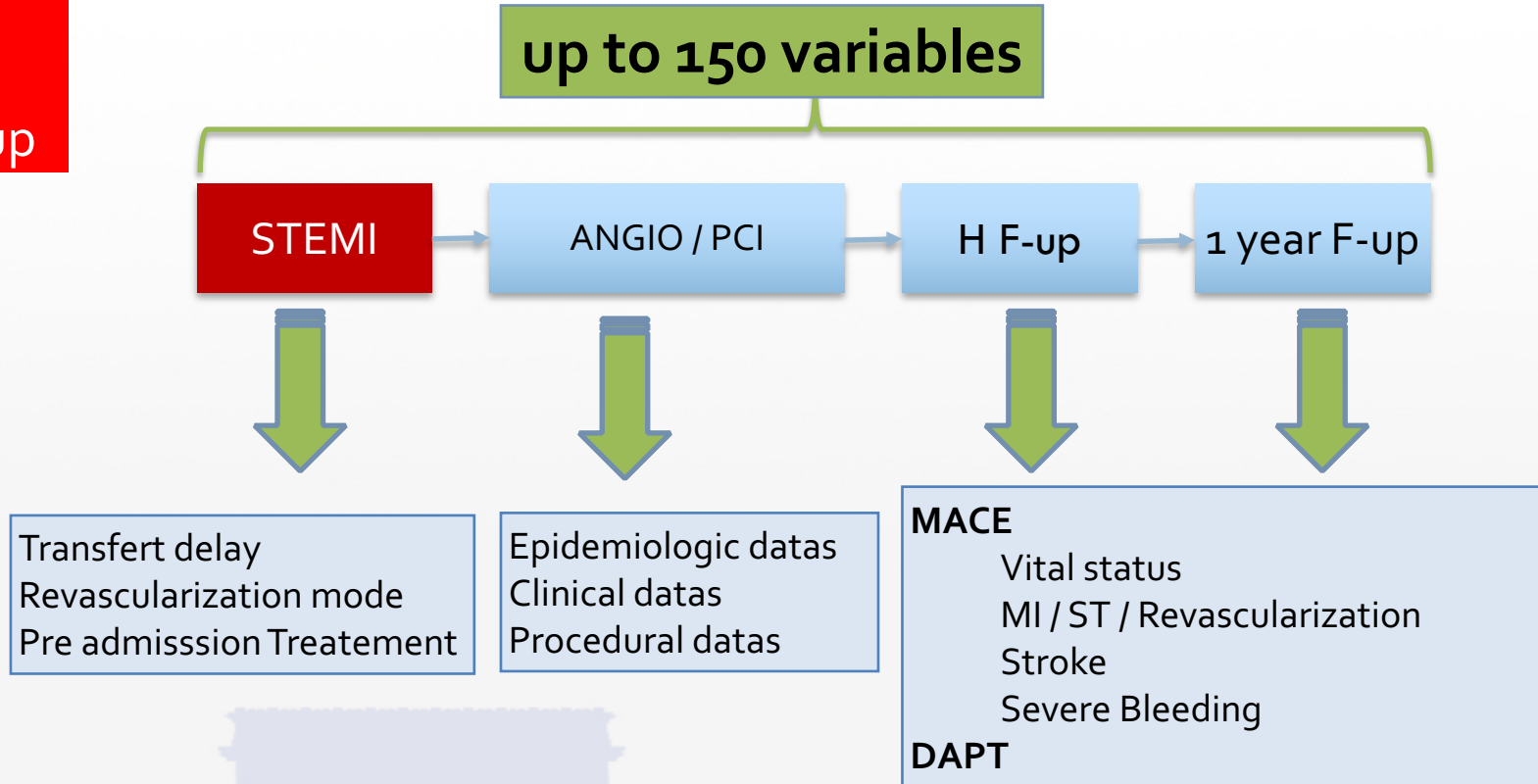
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# Which datas ?



- ✓ PCI registry
- ✓ STEMI registry
- ✓ One year follow-up





# Methodology = SCAAR like

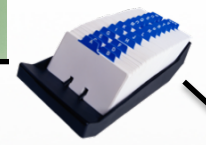


**Monitoring on site**

0,1 CRA / 250 PCI  
H F-up  
I year F-up



**Anonymisation**



https secured storage

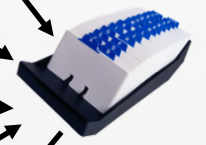


**Mandatory capture**

Local referent physician



- CHR Orléans
- Clinigrid
- CHG Bourges
- CVX
- CHG Chartres
- CVX
- CHU Tours
- CVX
- Reine Blanche
- CVX
- St Gatien
- CVX



100% CRA  
Monitoring  
Audit

**steering of registry  
Quality control**



# Methodology = SCAAR like



Monitoring on site

Anonymisation

0,1 CRA / 250 PCI  
H F-up



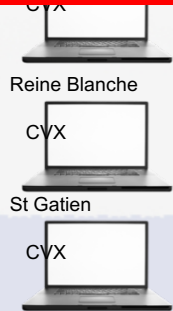
CHR Orléans



https secured storage

No double capture = no constraint for users  
Mandatory capture = exhaustivity  
Daily and electronic data transfer = interactivity  
F-up and monitoring by RCA = quality of data

Local referent physician



Reine Blanche

CVX

St Gatien

CVX



100% CRA  
Monitoring  
Audit

Coordination  
Quality control

# Quality of data Results



No double capture

Mandatory capture

CRA on site

**Procédure's Exhaustivity = 98 %**  
**2 % patient's agreement refusal**

**Attention!**  
 Données manquantes  
 Les champs suivants sont obligatoires:

Procédure:  
 • Contraste 1 ml  
 • Temps scopie  
 • PDS total  
 • AIR Kerma cumule

Veillez remplir ces champs obligatoires.

OK / Ignorer

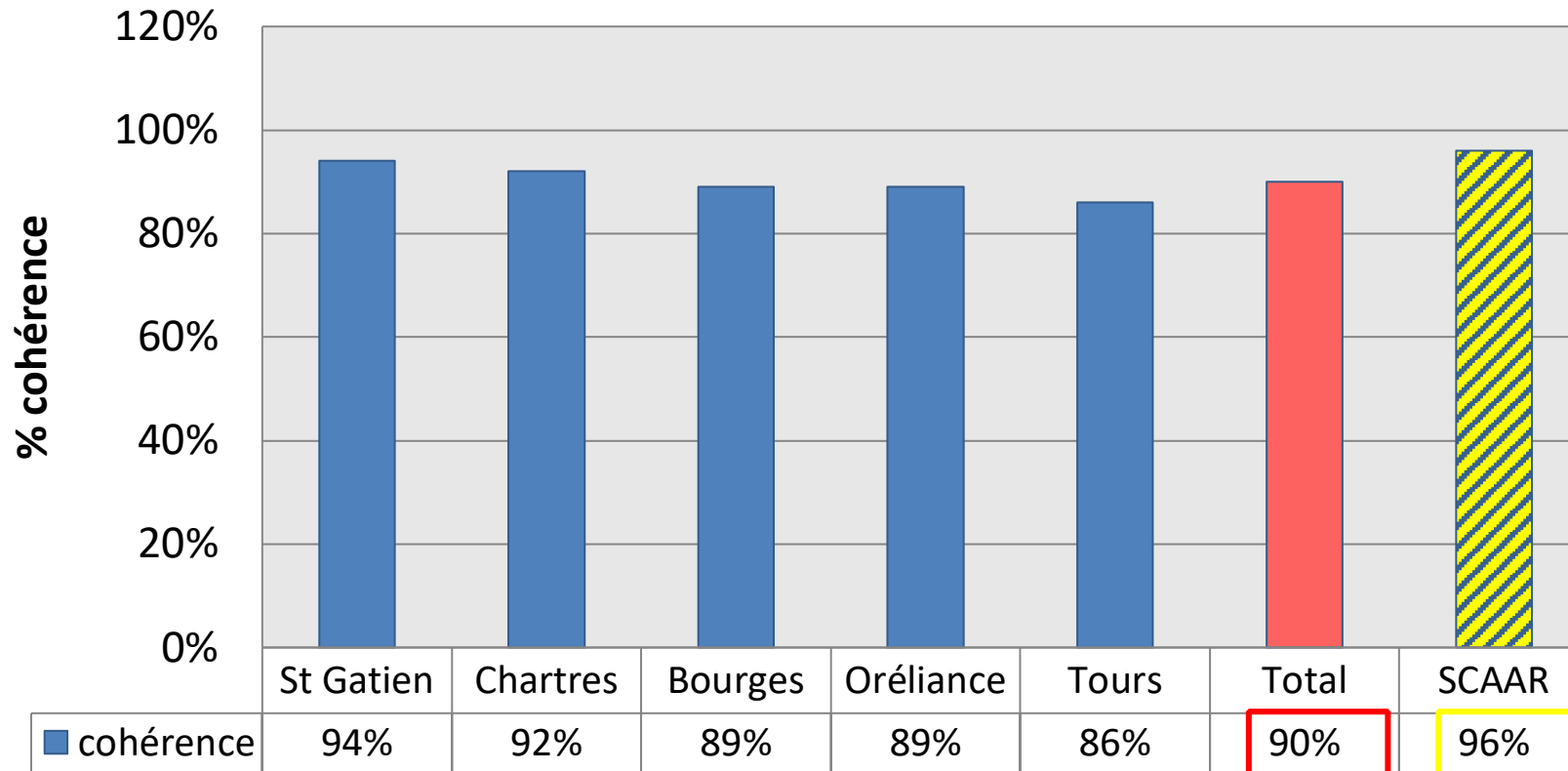
**Data's Exhaustivity > 99,6 %**

Date examen	Titre de l'examen	Proc.	Opérat.	Patient	%	Validation	Titré	% Suivi
01/03/2014	Coronarographie et Angi.	114859	Dr HA.	BERNARD SOLLIEZ	100%	Patient non...	CRA C	100%
02/03/2014	Coronarographie et Angi.	114863	Dr ALB.	LOUIS GRANDCOING	100%	Patient non...	CRA C	100%
02/03/2014	Coronarographie et Angi.	114873	Dr ALB.	GINETTE ANDRE	100%	Patient non...	CRA C	87%
03/03/2014	Coronarographie	114922	Dr RA.	JACQUES CARILLON	100%	Patient non...	CRA C	0%
03/03/2014	Angioplastie	114879	Dr RA.	PATRICK CHAVIGNY	100%	Patient non...	CRA C	100%
03/03/2014	Coronarographie	114887	Dr HA.	RENE TRONCON	100%	Patient non...	CRA C	0%
03/03/2014	Coronarographie	114896	Dr RA.	MARCEL BOUE	100%	Patient non...	CRA C	0%
03/03/2014	Coronarographie et Angi.	114907	Dr RA.	RAOUL LADANNE	100%	Patient non...	CRA C	100%
04/03/2014	Coronarographie	114949	Dr RA.	MARCELLE PUECH	100%	Patient non...	CRA C	0%
04/03/2014	Coronarographie	114963	Dr RO.	DANIELLE REVOLTE	100%	Patient non...	CRA C	0%
04/03/2014	Coronarographie	114968	Dr RA.	JOEL VIGER	100%	Patient non...	CRA C	0%
04/03/2014	Coronarographie	114976	Dr RO.	MICHEL TOUILLIE	100%	Patient non...	CRA C	0%

**One year F-up exhaustivity = 95 %**  
**< 5 % lost patient**

05/03/2014	Coronarographie	115047	Dr ALB.	JANNIE PELLETIER	100%	Patient non...	CRA C	0%
05/03/2014	Coronarographie	115051	Dr ALB.	GILBERT LEE	100%	Patient non...	CRA C	0%
05/03/2014	Coronarographie	115026	Dr ALB.	RAYMOND MASSOT	100%	Patient non...	CRA C	0%
05/03/2014	Coronarographie	115085	Dr ALB.	PIERRE LE ROUX	100%	Patient non...	CRA C	0%
05/03/2014	Coronarographie	115079	Dr ALB.	LIONEL TOSSANDIE	100%	Patient non...	CRA C	0%
06/03/2014	Coronarographie et Angi.	115113	Dr ALB.	CELINE BERTONA	100%	Patient non...	CRA C	100%
06/03/2014	Coronarographie et Angi.	115167	Dr ALB.	ALAN PIERRE GUENEZ	100%	Patient non...	CRA C	100%
06/03/2014	Coronarographie	115193	Dr KH.	RENE ALPIS	100%	Patient non...	CRA C	0%
06/03/2014	Coronarographie	115118	Dr ALB.	AHMED KEBALI	100%	Patient non...	CRA C	0%
06/03/2014	Coronarographie	115120	Dr ALB.	NICOLE ROUSSEL	100%	Patient non...	CRA C	0%

# Consistency of datas Results



# On line activity report Benchmarking

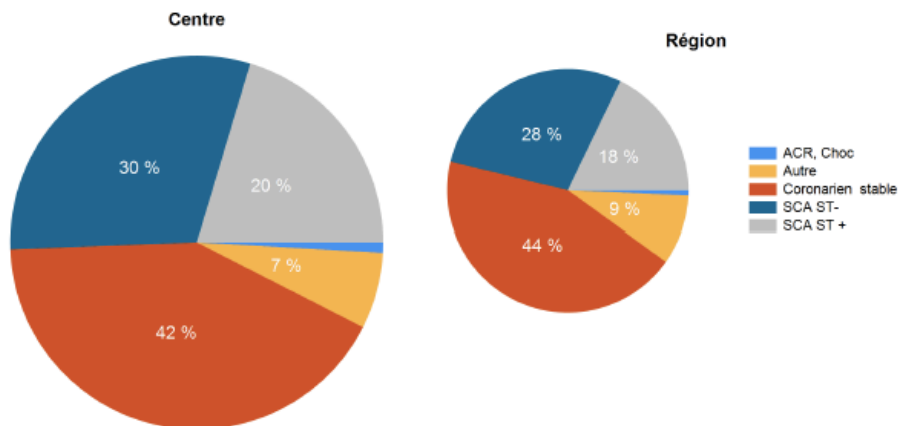


Rapport du 01/01/2016 au 30/04/2016

Total Examens réalisés	Centre	%	Région	%
Angioplasties adhoc	243	72.75%	2118	78.50%
Angioplasties seules	91	27.25%	580	21.50%
<b>Total</b>	<b>334</b>		<b>2698</b>	

## Données générales

Indications	Centre	%	Région	%
Coronarien stable	140	41.92%	1184	43.88%
SCA ST-	101	30.24%	766	28.39%
SCA ST +	68	20.36%	481	17.83%
ACR, Choc	3	0.90%	19	0.70%
Autre	22	6.59%	248	9.19%
<b>Total</b>	<b>334</b>		<b>2698</b>	

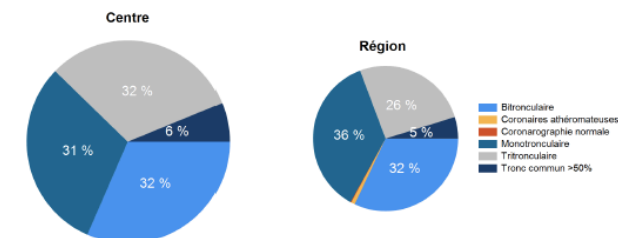


Rapport du 01/01/2016 au 30/04/2016

Données Cliniques	Centre	Région
Femme	20.7%	30.5%
HTA	58.1%	56.3%
Diabète	26.6%	26.0%
Tabac actif	56.0%	49.0%
Hérédité	24.3%	24.9%
Dyslipidémie	47.9%	44.8%
ATCD IDM	15.3%	16.6%
ATCD ATL	27.5%	34.9%
ATCD PAC	11.1%	7.0%
ATCD AVC	4.2%	14.7%
Pathologie vasculaire	6.9%	0.2%
Insuffisance rénale	9.6%	
Insuffisance rénale modérée	7.2%	
Insuffisance rénale sévère	1.2%	
Insuffisance rénale dialysée	1.2%	
IMC moyen (kg/m <sup>2</sup> )	27.41	

## Données Coronarographiques

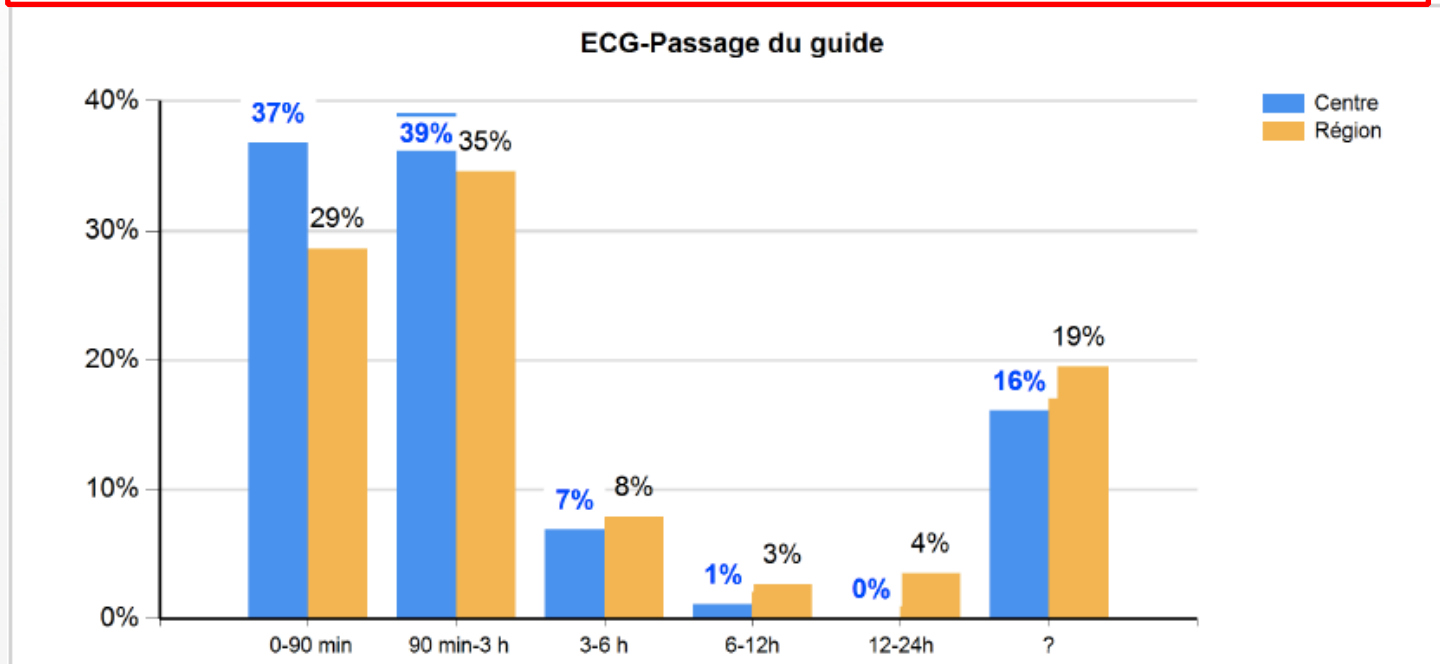
Nombre de troncs	Centre	%	Région	%
Coronarographie normale	0	0.00%	5	0.18%
Coronaires athéromateuses	0	0.00%	24	0.85%
Monotronculaire	109	30.70%	1019	36.24%
Bitronculaire	112	31.55%	900	32.01%
Tritronculaire	112	31.55%	729	25.92%
Tronc commun >50%	22	6.20%	135	4.80%
<b>Total</b>	<b>355</b>		<b>2812</b>	



# STEMI delays



Délai de prise en charge (mediane en min.)	Centre	Région
Douleur - ECG	100.5 min	95 min
ECG - Thrombolyse	65.5 min	24.5 min
ECG - Passage guide	95 min	106 min



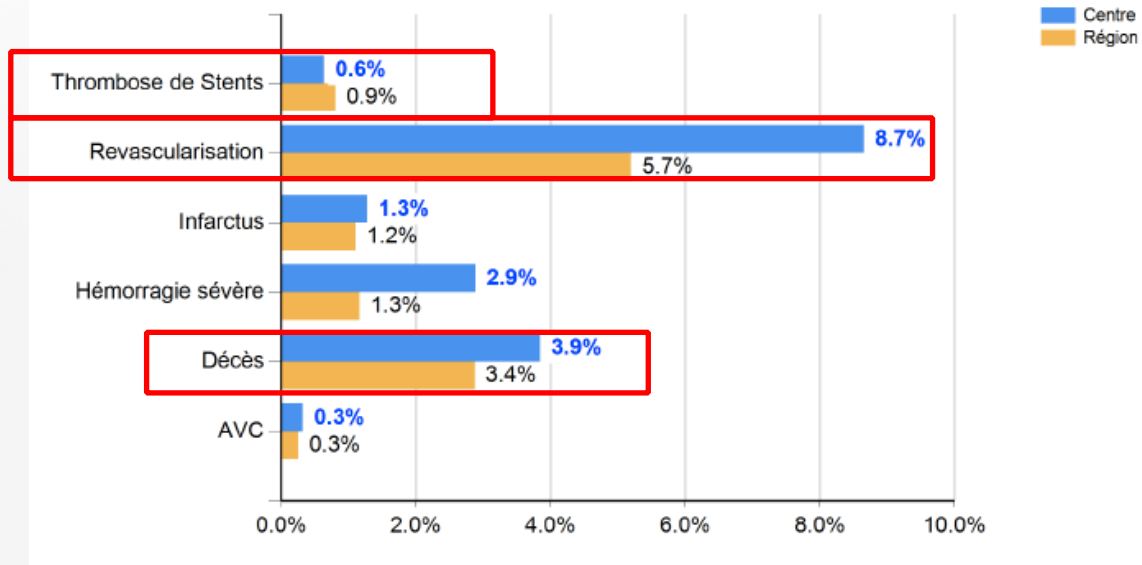


# One year MACE / SCAD













Angor Stable (Centre = 312 / Région = 1982)

Evènements majeurs suivi Hosp + à 1 an	Centre	% - n	Région	% - n
Infarctus	4	1.3% - 312	22	1.2% - 1802
Thrombose de Stents	2	0.6% - 312	16	0.9% - 1802
AVC	1	0.3% - 312	5	0.3% - 1802
Hémorragie sévère	9	2.9% - 312	23	1.3% - 1802
Revascularisation	27	8.7% - 312	103	5.7% - 1802
Décès	12	3.9% - 311	57	3.4% - 1675

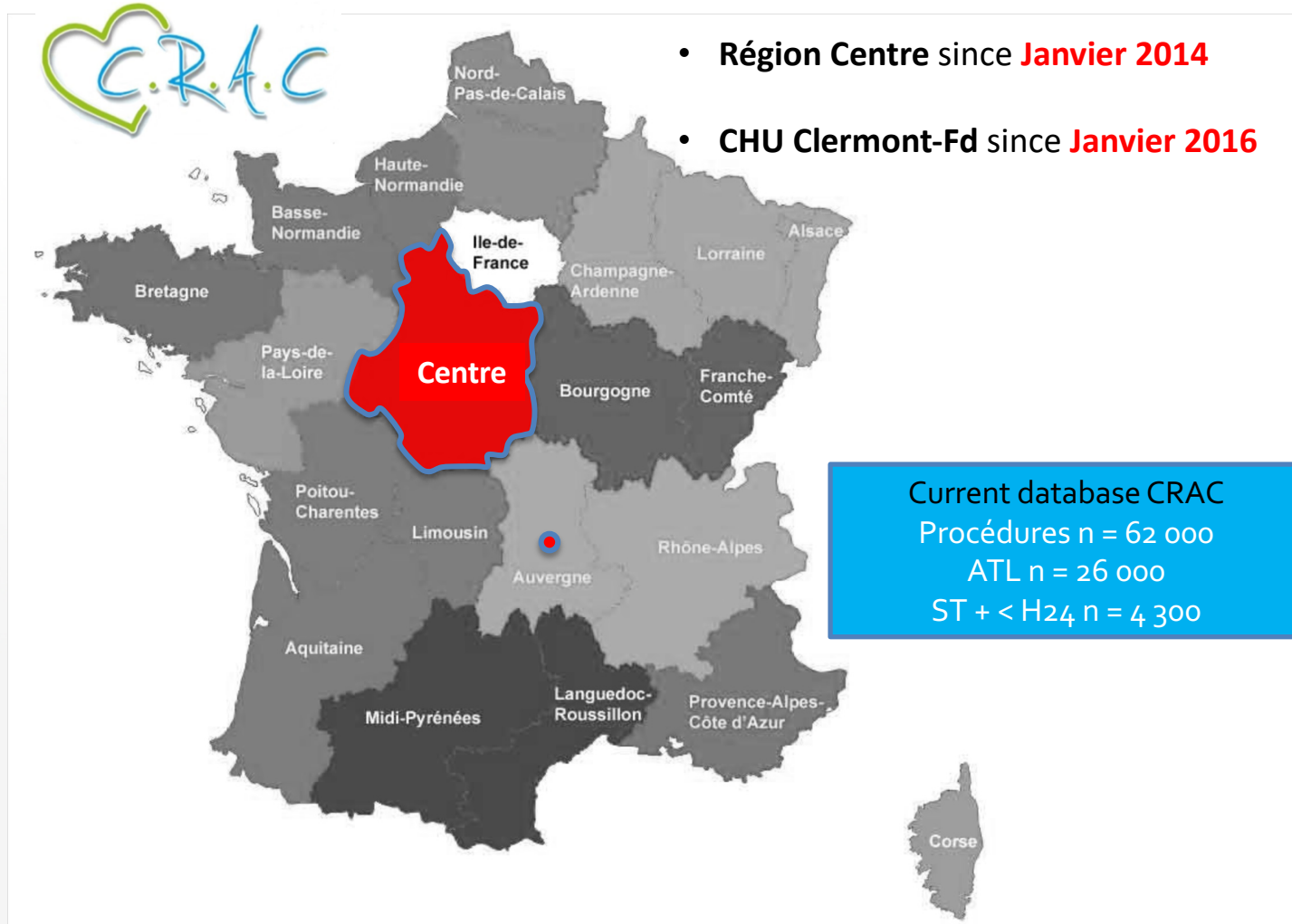




# Quality score index

Indicateurs	Centre		Région	Score
. Angor Stable: ATL sans ischémie documentée	18.4%		37.9%	1
. Angor Stable: ATL sans FEVG renseignée	2.0%		12.8%	1
. Performance: ATL par voie radiale (hors ST+)	95.1%		92.1%	1
. Performance: Délai (min.) ECG - Passage guide pour ST+	89		113	1
. Sécurité: Q. Contraste moyen (ml) coronarographies seules	86		75	0
. Sécurité: PDS total moyen (cGy.cm <sup>2</sup> ) coronarographies seules	2185.1		2468.22	1
. Prévention: Ticagrelor ou Prasugrel post ST+<24h	83.0%		74.8%	1
. Prévention: rééducation CV post ST+<24h	45.0%		46.5%	0
. Qualité: exhaustivité des procédures ATL (%)	99.89		97.62	1
. Qualité: exhaustivité des suivis hospitalier post ATL (%)	99.8		95.32	1
			<b>Total =</b>	<b>8 / 10</b>

# CRAC registry : Current state

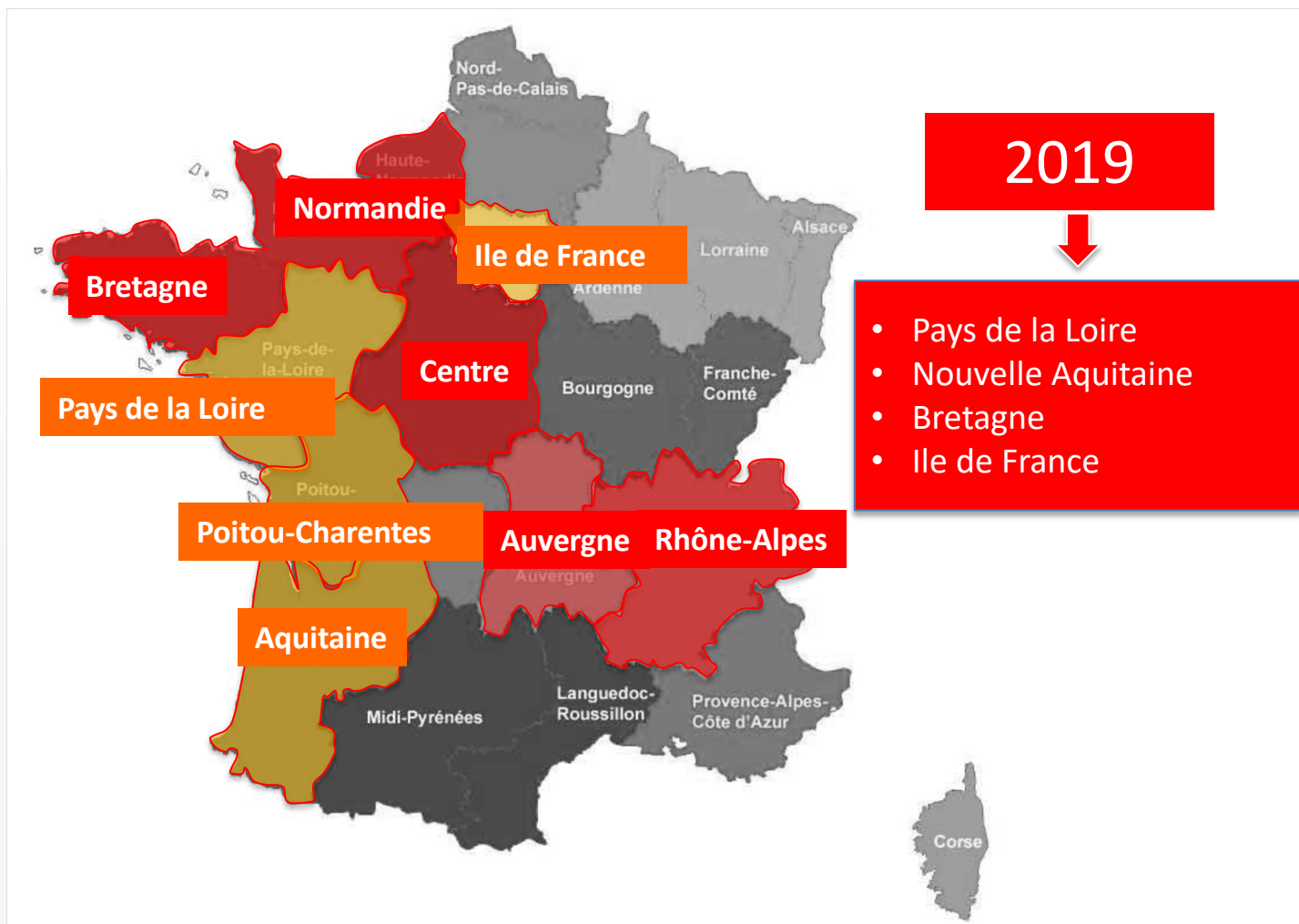


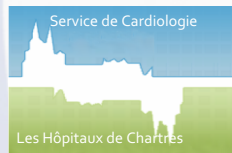
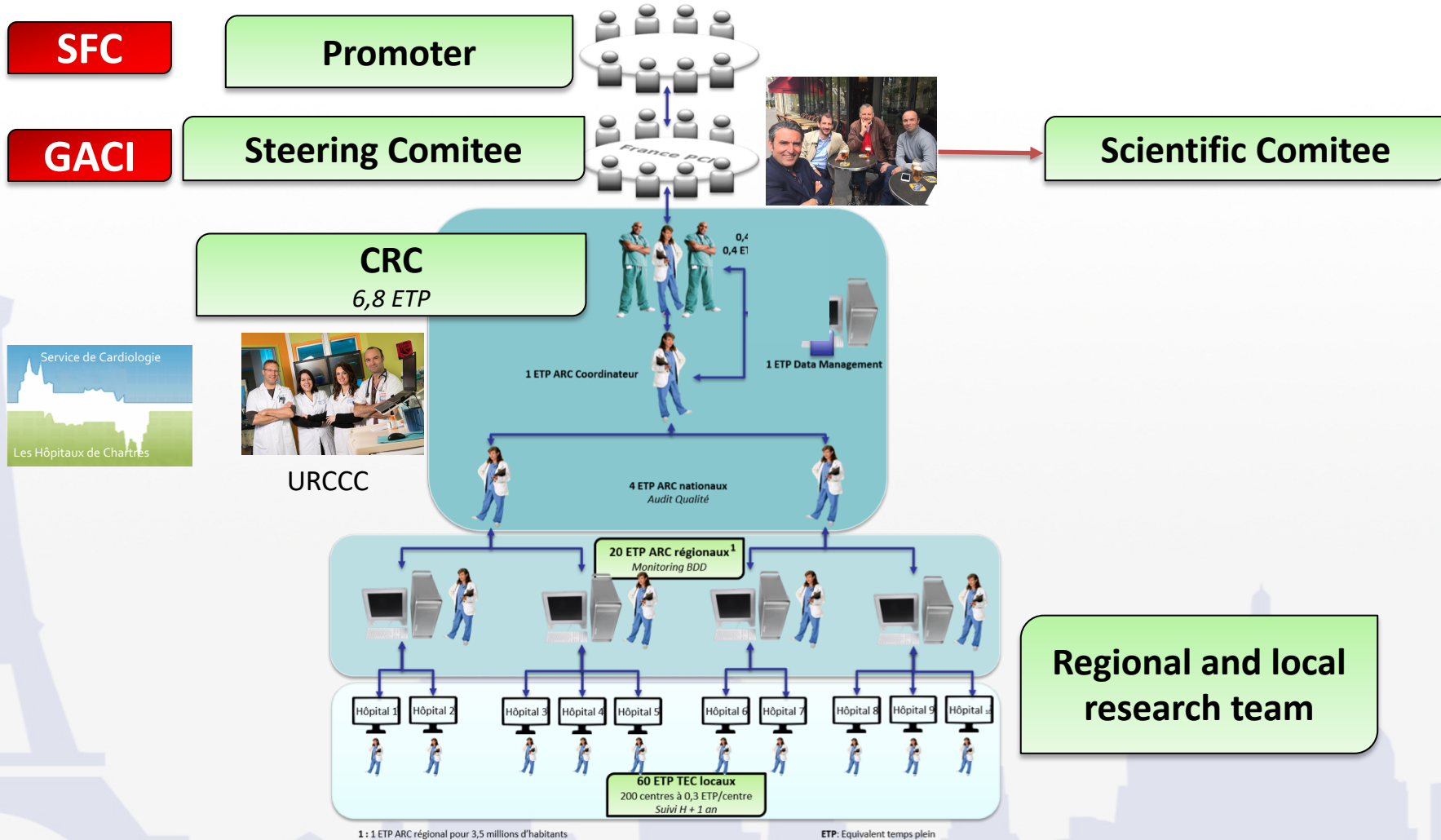
# France PCI = « National CRAC » Ongoing expansion (2018)

## GACI task force



# France PCI = National CRAC Future expansion (>2018)





URCCC

1 : 1 ETP ARC régional pour 3,5 millions d'habitants

ETP: Equivalent temps plein



Funding (CRAC registry)  
Institutionnal and Industrial financial support  
Operating cost = 150000 euros / year





# France – PCI (Business Plan) 100 % Institutionnal Funding DGOS and ARS



RESSOURCES HUMAINES ETP = Equivalent Temps Plein	2016	2017	2018	2019	2020	2021 +
<b>Nb régions actives (I)</b>	4	8	12	16	22	22
<b>Nb centres actifs</b>	40	80	120	160	200	200
<b>1- Personnel Equipe Projet (II) ARO : Academic Research Organisation</b>						
0,4 ETP Médecin coordinateur (80 € TTC/h = 2 560 € net/m)	61,4	61,4	61,4	61,4	61,4	61,4
0,4 ETP Chef de projet (60 € TTC /h = 1920 € net/m)	46,1	46,1	46,1	46,1	46,1	46,1
1 ETP ARC Coordinateur (35 € TTC /h = 2 800 € net/m)	67,2	67,2	67,2	67,2	67,2	67,2
1 ETP Data manager/Statisticien (35 € TTC /h = 2 800 € net/m)	67,2	67,2	67,2	67,2	67,2	67,2
1 ETP X 4 ARC contrôle qualité (n=4) (III) (25 € TTC /h = 2000 € net/m)		48,0	96,0	144,0	192,0	192,0
<b>Total personnel ARO = 6,4 ETP</b>	241,9	289,9	337,9	385,9	433,9	433,9
<b>2- Personnel</b>						
ARC = Attaché TEC = Technicien						
1 ETP ARC/3,5M habitants soit 20 ARC ETP (IV) (23 € TTC/h = 44160 € = 1840 € net/m)	176,6	353,3	529,9	706,6	971,5	971,5
0,3 ETP TEC local X 200 centres = 60 ETP (V) (20 € TTC /h x 0,3 = 11 520 € = 480 € net/m)	460,8	921,6	1 382,4	1 843,2	2 304,0	2 304,0
<b>Total personnel Régions et Centres = 80 ETP</b>	637,4	1 274,9	1 912,3	2 549,8	3 275,5	3 275,5
<b>Total personnel ARO + Régions + Centres</b>	879,4	1 564,8	2 250,2	2 935,7	3 709,4	3 709,4

Total cost = 3710 k€ /an

# Expensive ?

Budget 4M / year  
400 000 procedures whose 170 000 PCI et 30 000 STEMI  
150 variables and one year follow-up

France PCI cost : 10 euros / procédure

phase 3 study median cost : 26 000 euros / patient

# France PCI supports

- GACI / SFC (forward promoter)
- EAPCI
- Ministry of health (DGOS) : Mme Julienne / Pr Thuillez
  - National part funding
- > 80 % of cath labs in France engaged
- Leaders in IC : Pr Montalescot / Pr Steg / Pr Danchin / ...
- Regional health agency :
  - Regional part funding

# Conclusions



- CRAC is a regional registry of IC
  - Steered by interventional cardiologists
  - Already operational in région Centre Val de Loire since 2014 and CHU Clermont since 2016
  - With high quality of data
  - « Low cost »
  - Base for ongoing National French registry of IC , France PCI, with planned extension to Normandy and Auvergne Rhône Alpes in 2018
  - Supported by
    - IC community
    - SFC /GACI
    - DGOS
    - and Regional Health Agencies
  - Essential for
    - Patients by improving quality of care and prognosis of CAD
    - Cardiologists (assessment of practice, Benchmarking, publications,...)
    - Administration of Health (quality of care, pertinence of care, health warning, medico-economic analysis,..)

www.francepci.com



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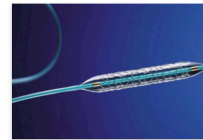
Siège Social du CRAC:

7 Rue Jules Moinaux  
37000 Tours

Logistique "Registre CRAC-  
France PCI":

Unité de Recherche Clinique  
de Cardiologie

Sélectionner une langue ▼



Le registre CRAC, dont la méthodologie s'est fortement inspirée du registre suédois SCAAR, est un observatoire de cardiologie interventionnelle initié en 2014 en région Centre Val de Loire sur 6 centres de coronarographie, porté par les cardiologues (association CRAC) et dont l'équipe projet dépend de l'unité de recherche du service de cardiologie de l'hôpital de Chartres.

Devant son succès, il va s'étendre à d'autres régions en France et, à terme, à l'ensemble du territoire national pour devenir le registre