



Organizing of National Registry of Interventional Cardiology France PCI experience

« More we share , more we have »

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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 :

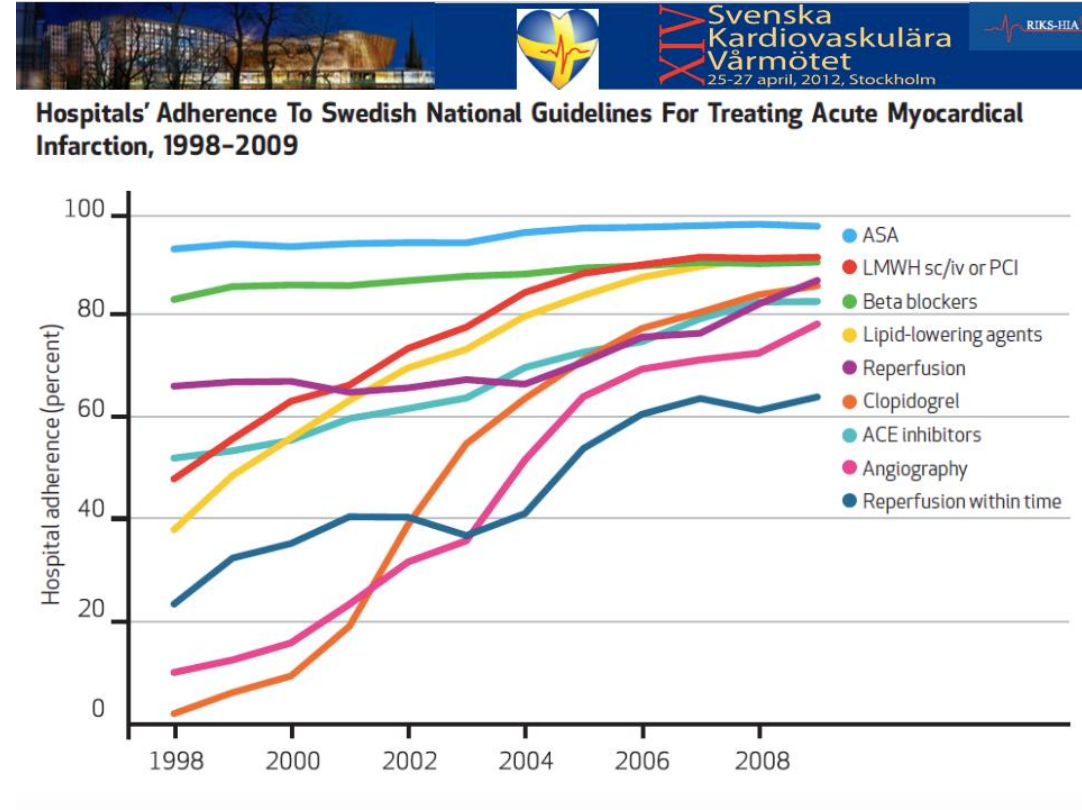
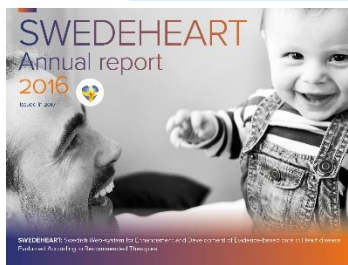
Potential conflict of interest to declare :

Astra-Zeneca, Bayer, BMS, Biotronik, Abbott

Why ?

Aim

Improve medical practice



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, celiac samples: March 5, n=28,190 unique set (*Circulation*. 2011;123:483-490.)

Association Between Admission Supine Systolic Blood Pressure and 1-Year Mortality in Patients With Myocardial Infarction

Frederik H. Sørensen, MD, PhD
Objective To study long-term mortality related to supine BP in patients admitted to the medic.
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 (SWEDHEART)

Karinna Sörensen, MD; Pia Lindman, MD, PhD; Stefan H. Jacobson, MD, PhD; Stefan Schön, MD; Johan Lindbäck, MSc; Ulf Stenestrand, MD, PhD; Lars Wallentin, MD, PhD; Tomas Jernberg
(*Circulation*. 2009;120:851-858.)



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, M.Sc.; Jörg Carlsson, M.D., Ph.D.; Fredrik Schersten, M.D., Ph.D.; Tage Nilsson, M.D., Ph.D.; Lars Wallentin, M.D., Ph.D.; and Bo Lagerqvist, M.D., Ph.D., for the SCAAR Study Group

IN: 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, M.Sc.; 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

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 Randomised trials of early revascularisation in acute coronary syndromes have yielded conflicting results

Introduction

Results of randomised trials on the survival benefits of early revascularisation after acute coronary syndromes are inconclusive. *Lancet* 2002; 359: 1805-11

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

Thomas Jernberg, MD, PhD
Pia Johansson, MD, PhD
Gunn HALL, MD, PhD

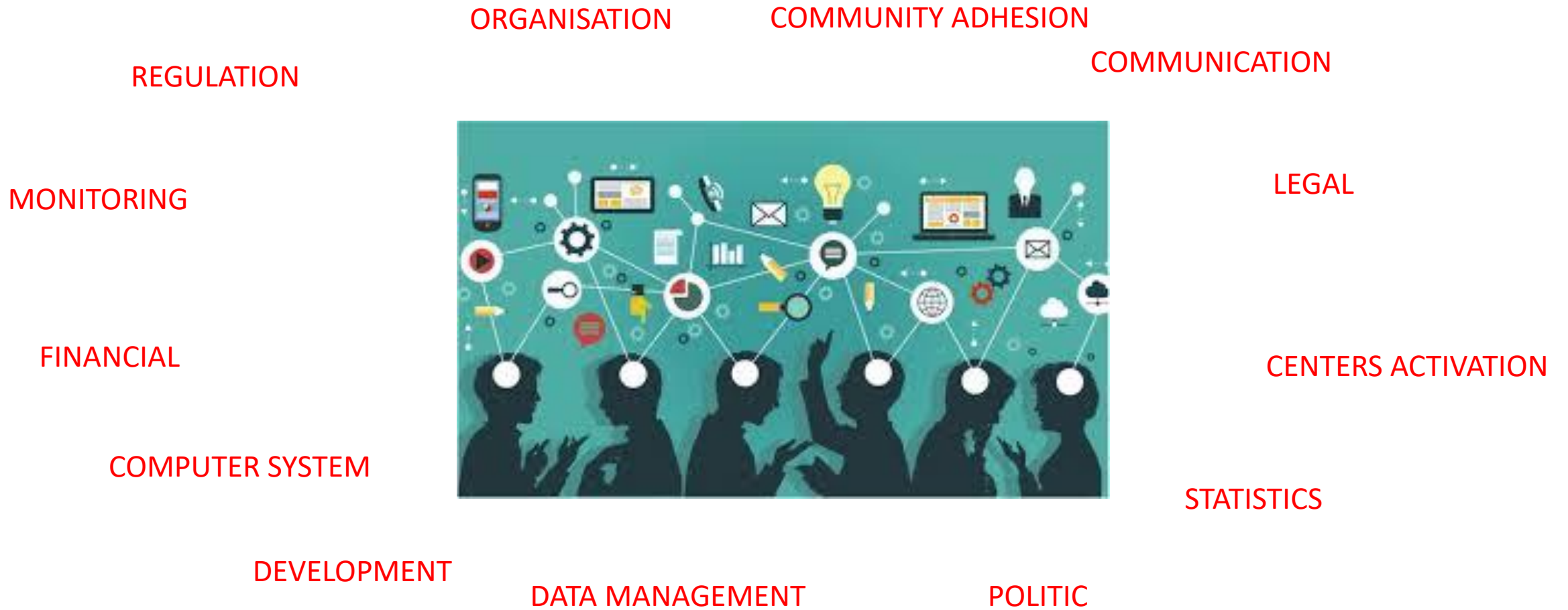
Context Only limited information is available on the need of implementation of new evidence-based and guideline in real life health care. *JAMA*. 2011;305(16):1677-1684

40 high rank publications/year

How ?

Hard job !

So many obstacles



Specifications

Key points



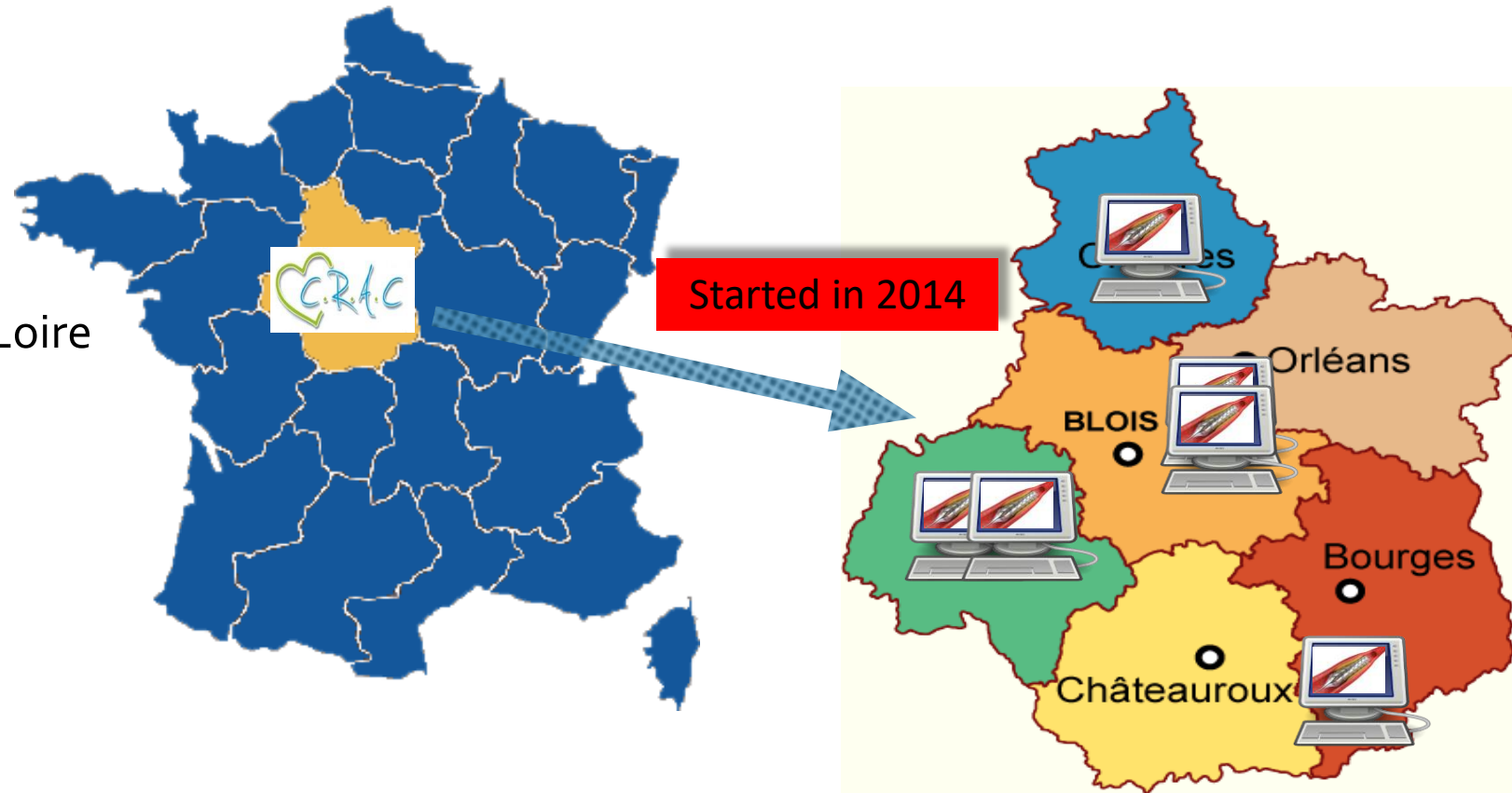
- ✓ Project leader(s) : Unifying and motivated interventional cardiologists
- ✓ Data base steer and own by cardiologic community
- ✓ Start with a regional experience and step by step national deployment
- ✓ Easy data capture with full integrated electronic solution with daily update
- ✓ High quality of datas
- ✓ « Long » term clinical follow-up
- ✓ Users adherence with access to website database
- ✓ Institutionnal and private funding

CRAC Registry

Club Régional des Angioplasticiens du Centre

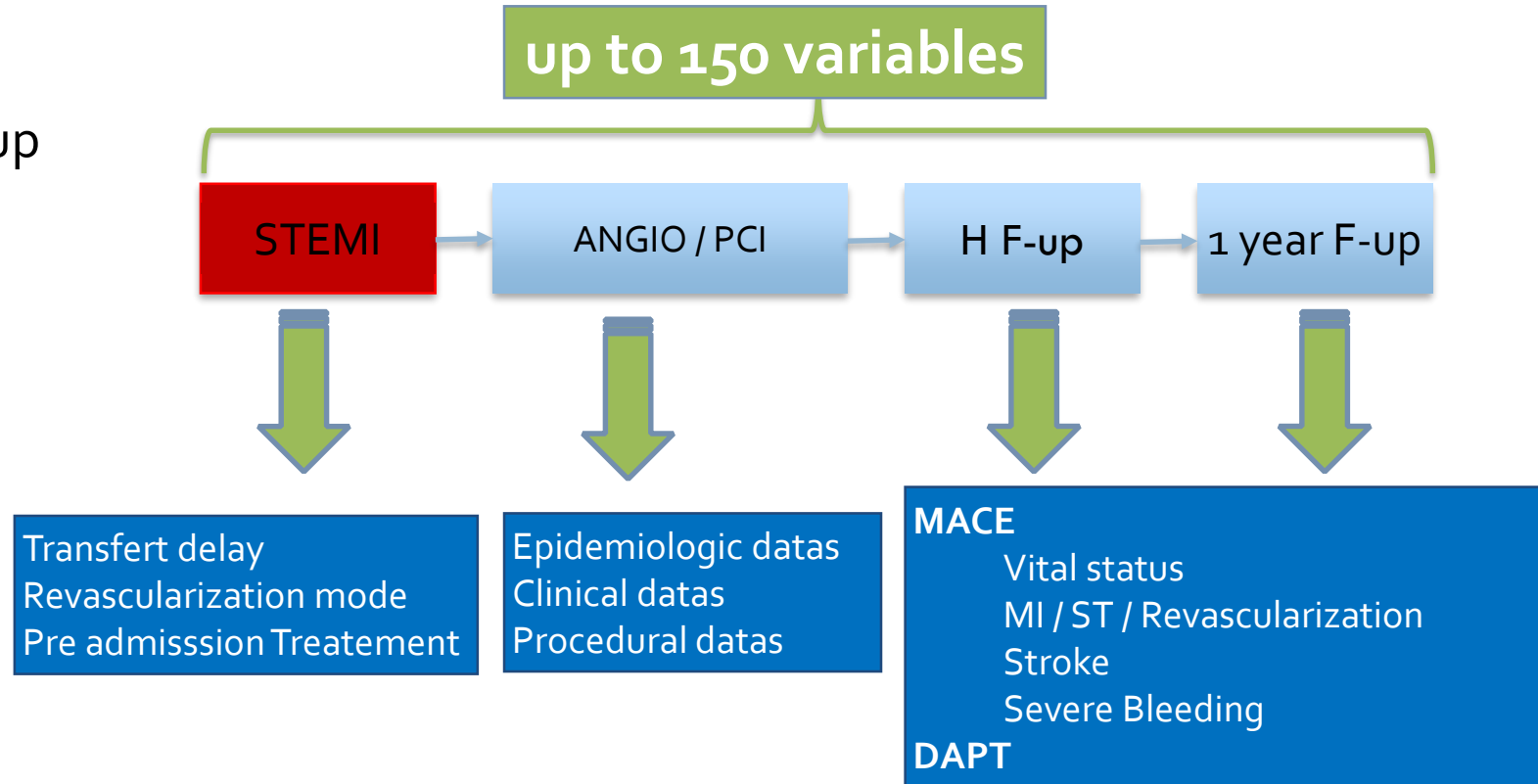


Région Centre Val de Loire
2,5 M of people
6 cath labs
Annual Activity
13000 procedures
5000 PCI
1000 STEMI < H24

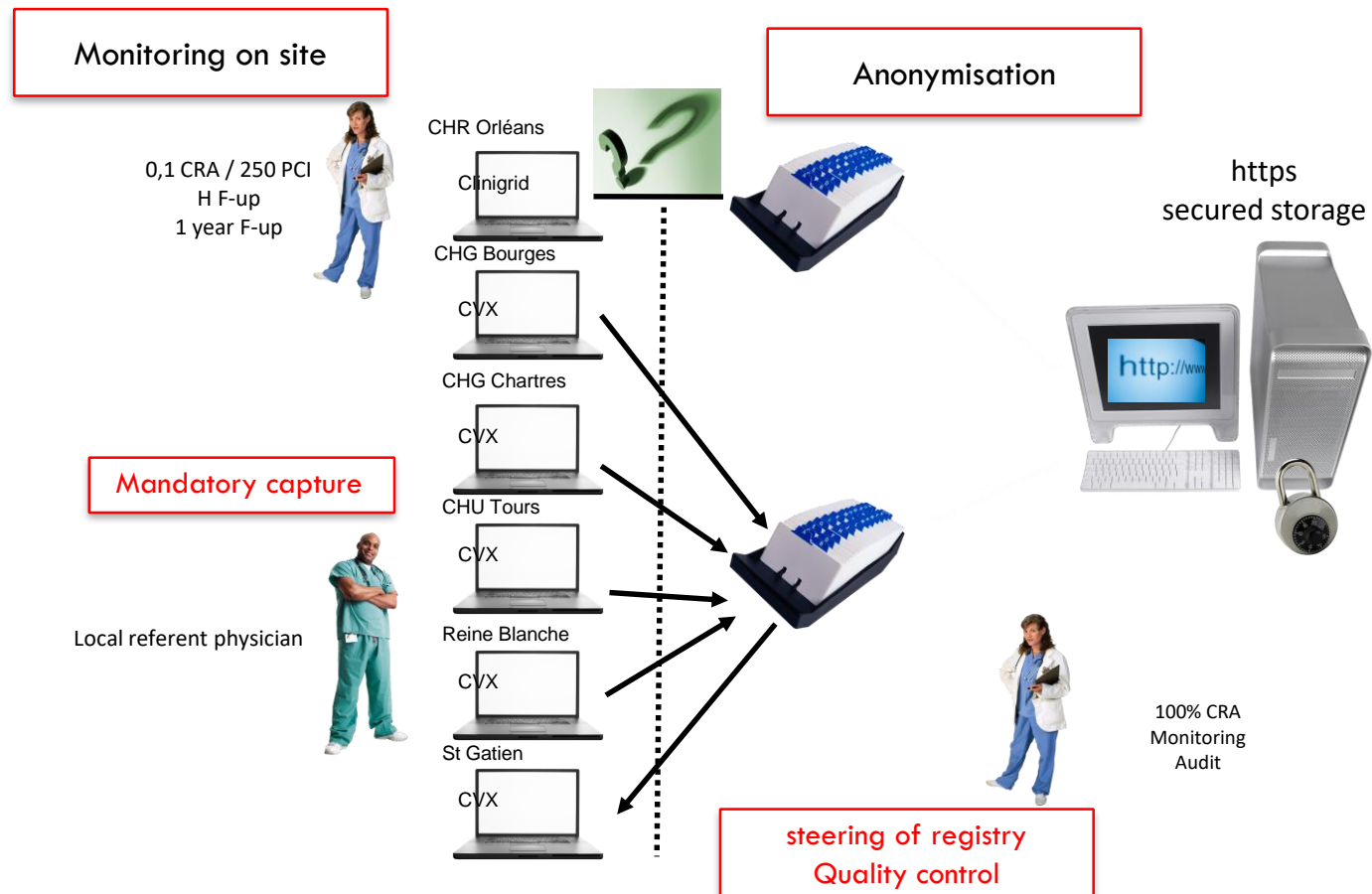


Which datas ?

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



Methodology = SCAAR like



Methodology = SCAAR like

Monitoring on site

Anonymisation

0,1 CRA / 250 PCI
H F-up

CHR Orléans

Clinigrid

https
secured storage

No double capture = no constraint for users

Mandatory capture = exhaustivity

Database daily update

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

Entrée salle ☐ Début proc. ☐ Fin proc. ☐ Sortie salle ☐

Degré d'urgence ☐ Statut d'hospitalisation ☐ Provenance ☐ Astreinte ☐ Public ou Privé ☐

N° de séjour

Archive N°

Taille cm Poids kg BMI SC

Protocole Contraste ml

Consentement du patient ☐

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

Mandatory capture

Attention!

Données manquantes
Les champs suivants sont obligatoires:

Procédure:

- Contraste ml
- Temps scopie
- PDS total
- AIR Kerma cumule

Veuillez remplir ces champs obligatoires.

OK

Support ☐ UF Provenance ☐

Archive N°

Taille cm Poids kg BMI SC

Protocole Contraste ml

Consentement du patient ☐

Data's Exhaustivity > 99,6 %

CRA on site

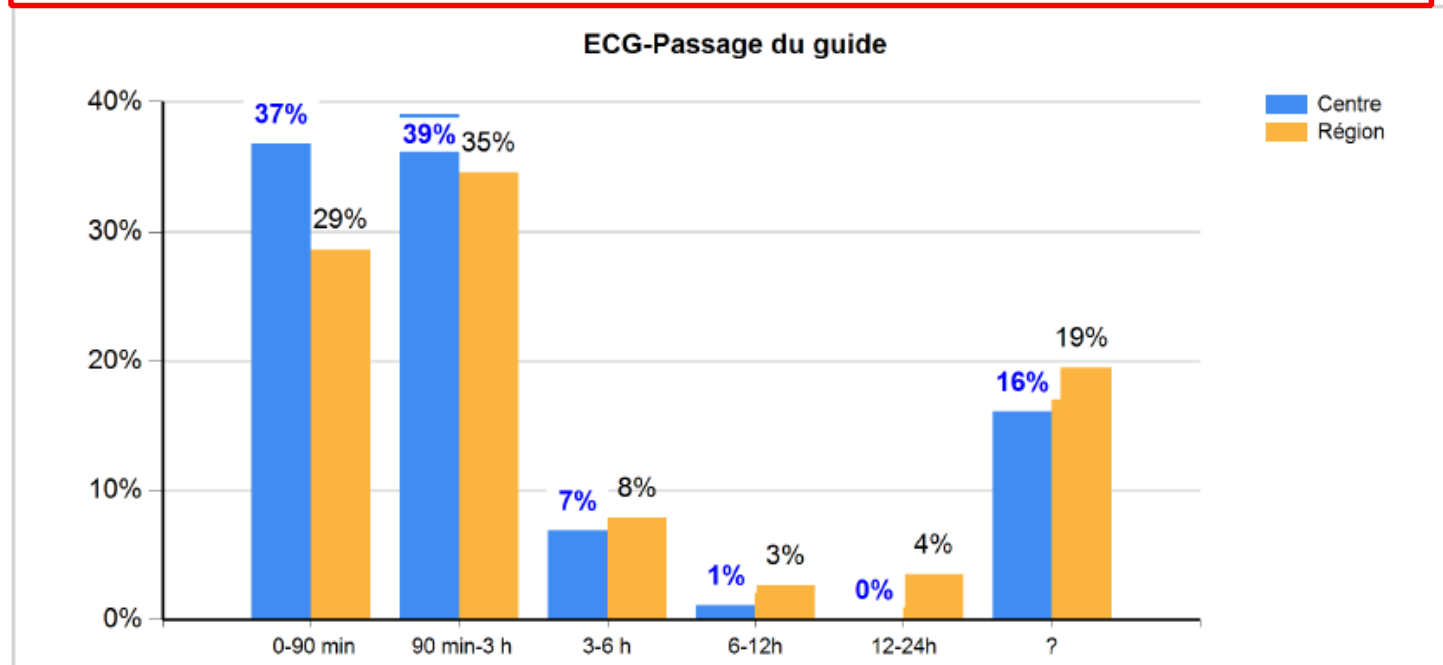
Date examen	Titre de l'examen	Proc.	Opérat.	Patient	%	Validation	Titre	% Suivi H
01/03/2014	Coronarographie et Ang.	114059	Dr HA.	BERNARD SOLLIEZ	100 %	Patient non	CRA	100 %
02/03/2014	Coronarographie et Ang.	114069	Dr ALB.	LOUIS GRANDCOING	100 %	Patient non	CRA	100 %
02/03/2014	Coronarographie et Ang.	114073	Dr ALB.	GINETTE ANDRE	100 %	Patient non	CRA	87 %
03/03/2014	Coronarographie	114022	Dr RA.	JACQUES CARILLON	100 %	Patient non	CRA	0 %
03/03/2014	Angioplastie	114079	Dr RA.	PATRICK CHAVIGNY	100 %	Patient non	CRA	100 %
03/03/2014	Coronarographie	114087	Dr HA.	RENE TRONCON	100 %	Patient non	CRA	0 %
03/03/2014	Coronarographie	114096	Dr RA.	MARCEL BOUE	100 %	Patient non	CRA	0 %
03/03/2014	Coronarographie et Ang.	114007	Dr RA.	RAOUL LADANNE	100 %	Patient non	CRA	100 %
04/03/2014	Coronarographie	114949	Dr RA.	MARCELLE PUECH	100 %	Patient non	CRA	0 %
04/03/2014	Coronarographie	114963	Dr RO.	DANIELLE REVOLTE	100 %	Patient non	CRA	0 %
04/03/2014	Coronarographie	114968	Dr RA.	JOEL VIGIER	100 %	Patient non	CRA	0 %
04/03/2014	Coronarographie	114976	Dr RO.	MICHEL TOURAILLE	100 %	Patient non	CRA	0 %
05/03/2014	Coronarographie	115047	Dr ALB.	JANINE PELLETIER	100 %	Patient non	CRA	0 %
05/03/2014	Coronarographie	115051	Dr ALB.	GILBERT LEE	100 %	Patient non	CRA	0 %
05/03/2014	Coronarographie	115056	Dr ALB.	RAYMOND MASSOT	100 %	Patient non	CRA	0 %
05/03/2014	Coronarographie	115065	Dr ALB.	PIERRE LE ROUX	100 %	Patient non	CRA	0 %
05/03/2014	Coronarographie	115079	Dr ALB.	LIONEL TISSANDIE	100 %	Patient non	CRA	0 %
06/03/2014	Coronarographie et Ang.	115113	Dr ALB.	CELANE BERTONA	100 %	Patient non	CRA	100 %
06/03/2014	Coronarographie et Ang.	115167	Dr ALB.	ALAIN PIERRE GUENEZ	100 %	Patient non	CRA	100 %
06/03/2014	Coronarographie	115193	Dr KM.	RENE ALUPS	100 %	Patient non	CRA	0 %
06/03/2014	Coronarographie	115118	Dr ALB.	AHMED KEBALI	100 %	Patient non	CRA	0 %
06/03/2014	Coronarographie	115120	Dr ALB.	NICOLE ROUSSEL	100 %	Patient non	CRA	0 %

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

Benchmarking by on line activity report

STEMI delays

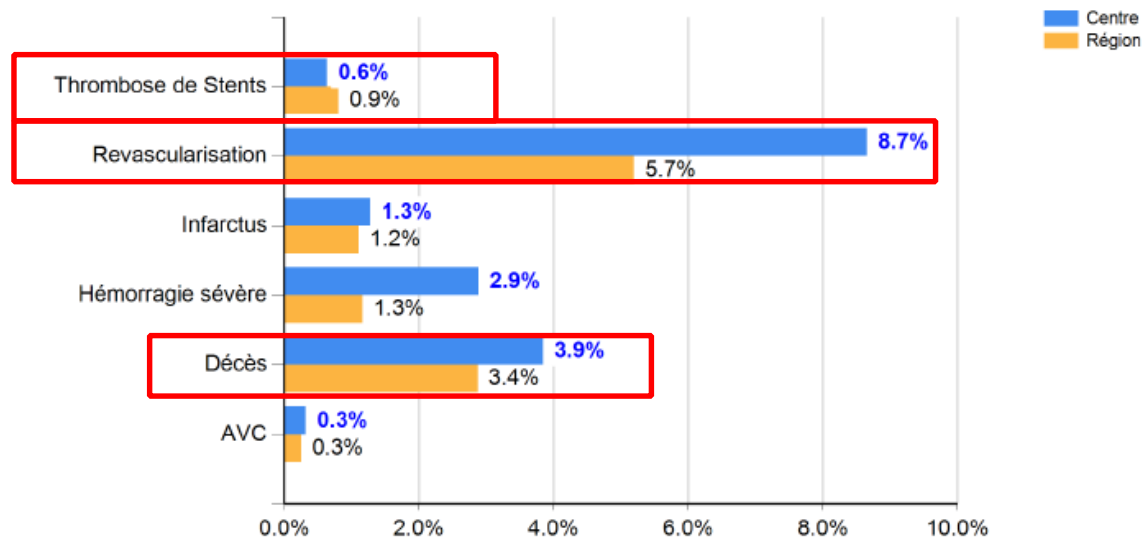
Délai de prise en charge (mediane en min.)	Centre	Région
Douleur - ECG	100.5 min	95 min
ECG - Thrombolyse	65.5 min	24.5 min
ECG - Passage guide	95 min	106 min



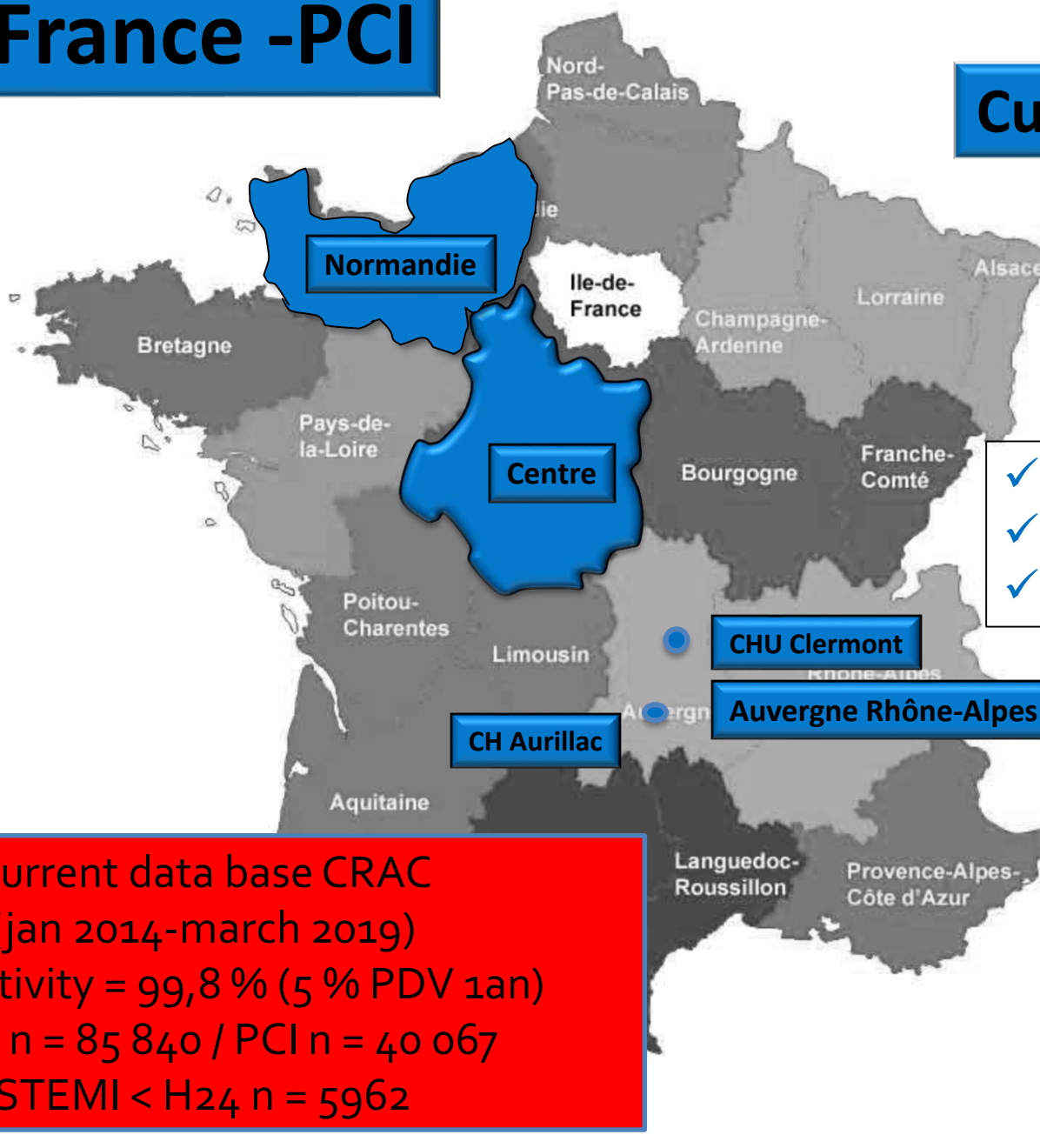
One year MACE / SCAD

Angor Stable (Centre = 312 / Region = 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



Current state March 2019



13 active centres
About 6 Millions people area
10 % french population

- ✓ Centre Val de Loire (n=6/6)
- ✓ Normandie (n=5/7)
- ✓ Auvergne Rhône Alpes (n=2)

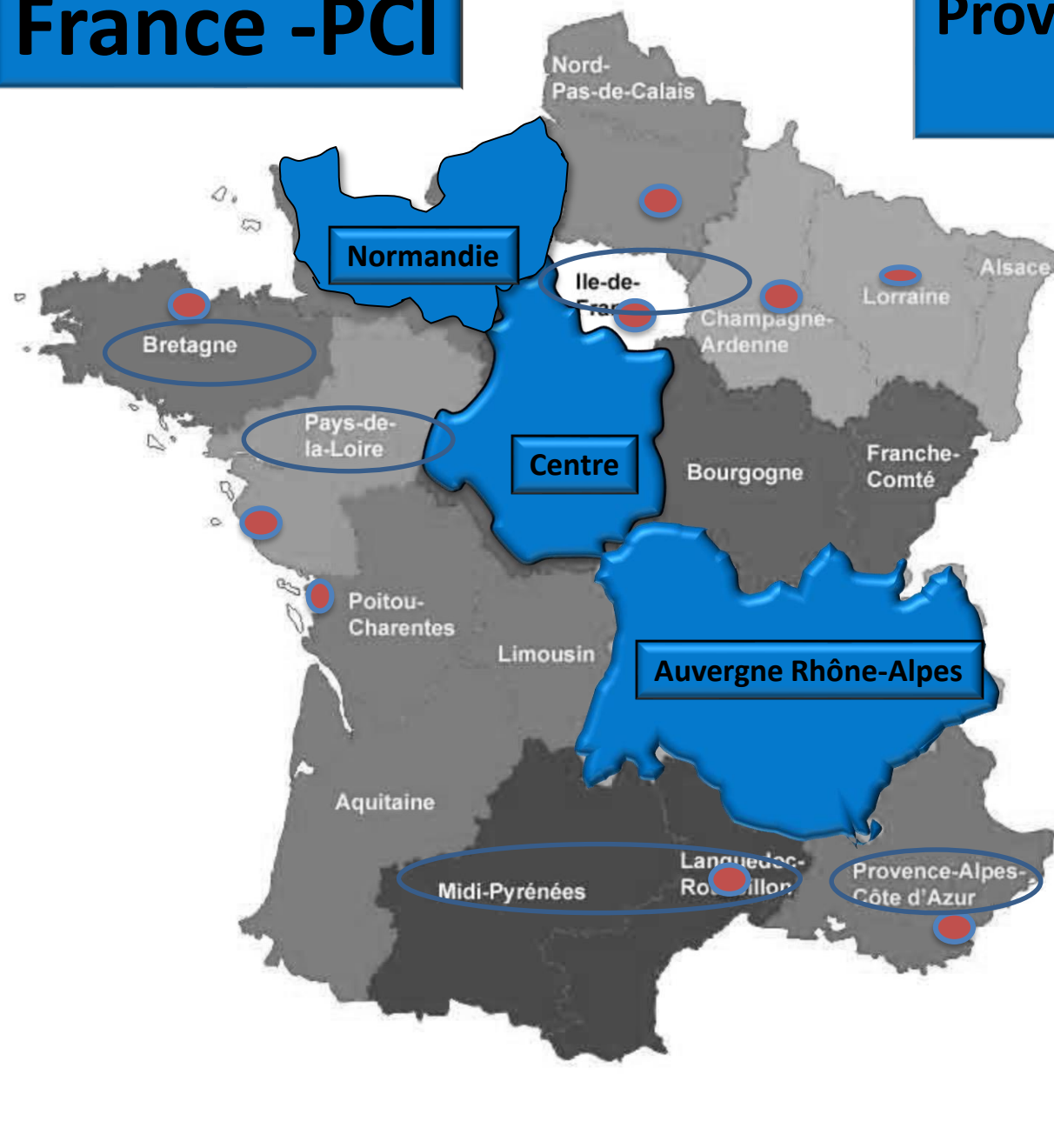
Current data base CRAC

(jan 2014-march 2019)

Exhaustivity = 99,8 % (5 % PDV 1an)

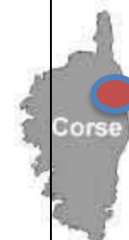
Coro n = 85 840 / PCI n = 40 067

STEMI < H24 n = 5962



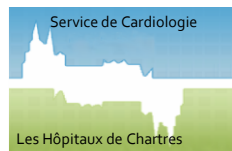
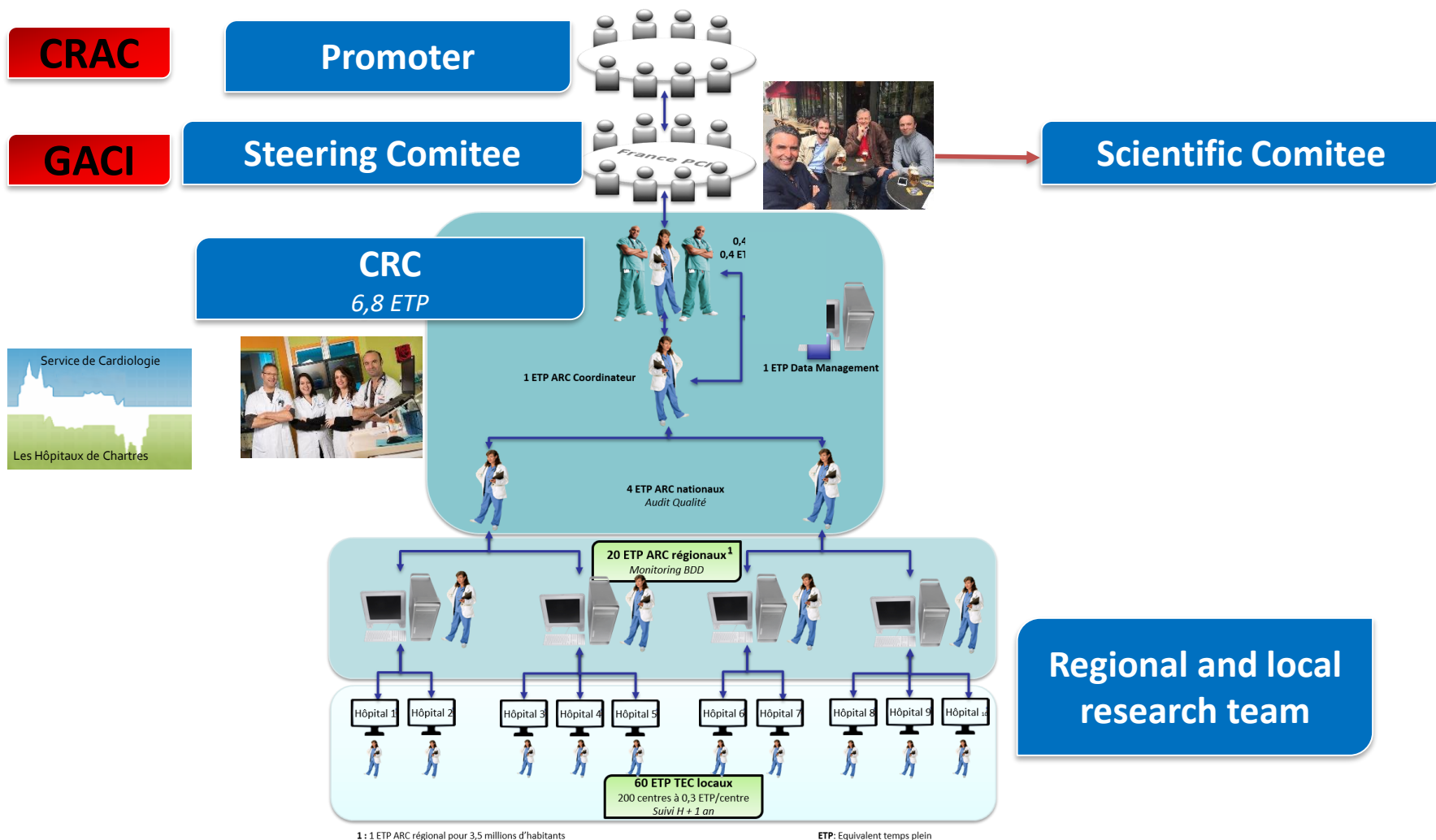
**30 Actives centers
= SCAAR**

- ✓ Centre Val de Loire (n=6/6)
- ✓ Normandie (n=7/7)
- ✓ Auvergne Rhône Alpes (n=11/21)
- ✓ Autres :
 - ✓ La Roche sur Yon
 - ✓ CH Metz
 - ✓ IMM
 - ✓ Clinique de la Roseraie
 - ✓ Clinique A Paré
 - ✓ Saint Brieuc
 - ✓ Bastia
 - ✓ La Rochelle
 - ✓ Amiens
 - ✓ Reims
 - ✓ ...



France PCI Organisation

GACI



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

Factors associated with delay in transfer of patients with ST-segment elevation myocardial infarction from first medical contact to catheterization laboratory: Lessons from CRAC, a French prospective multicentre registry

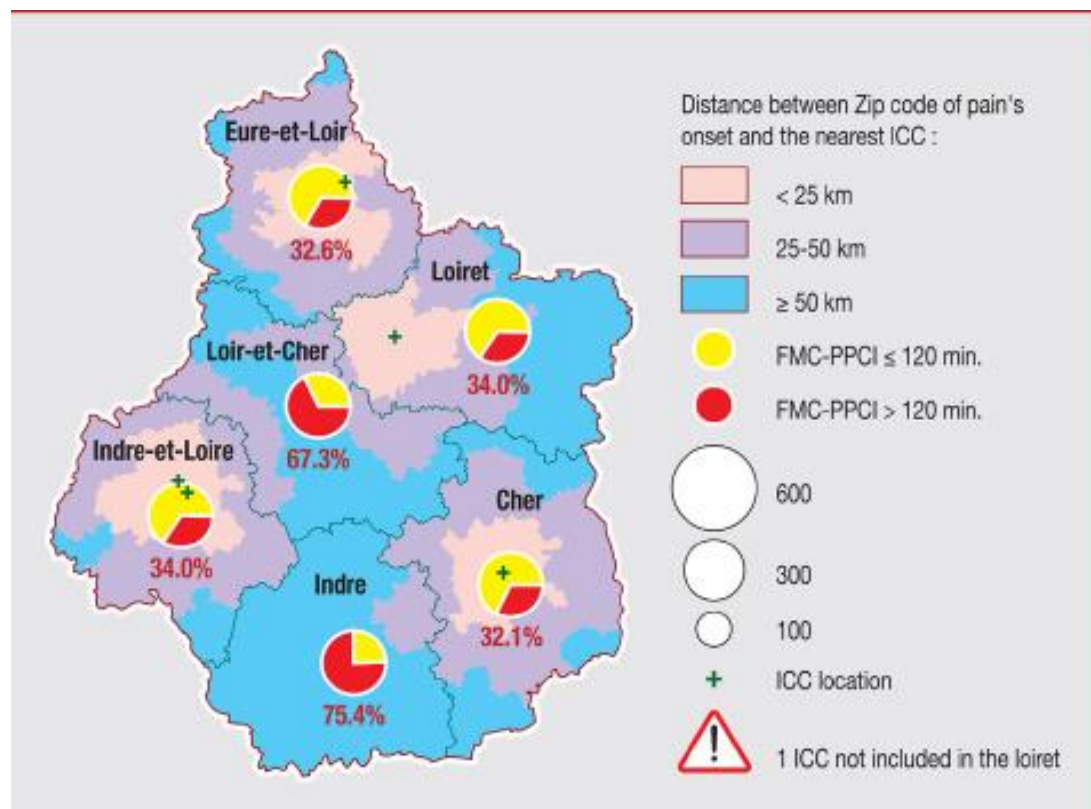
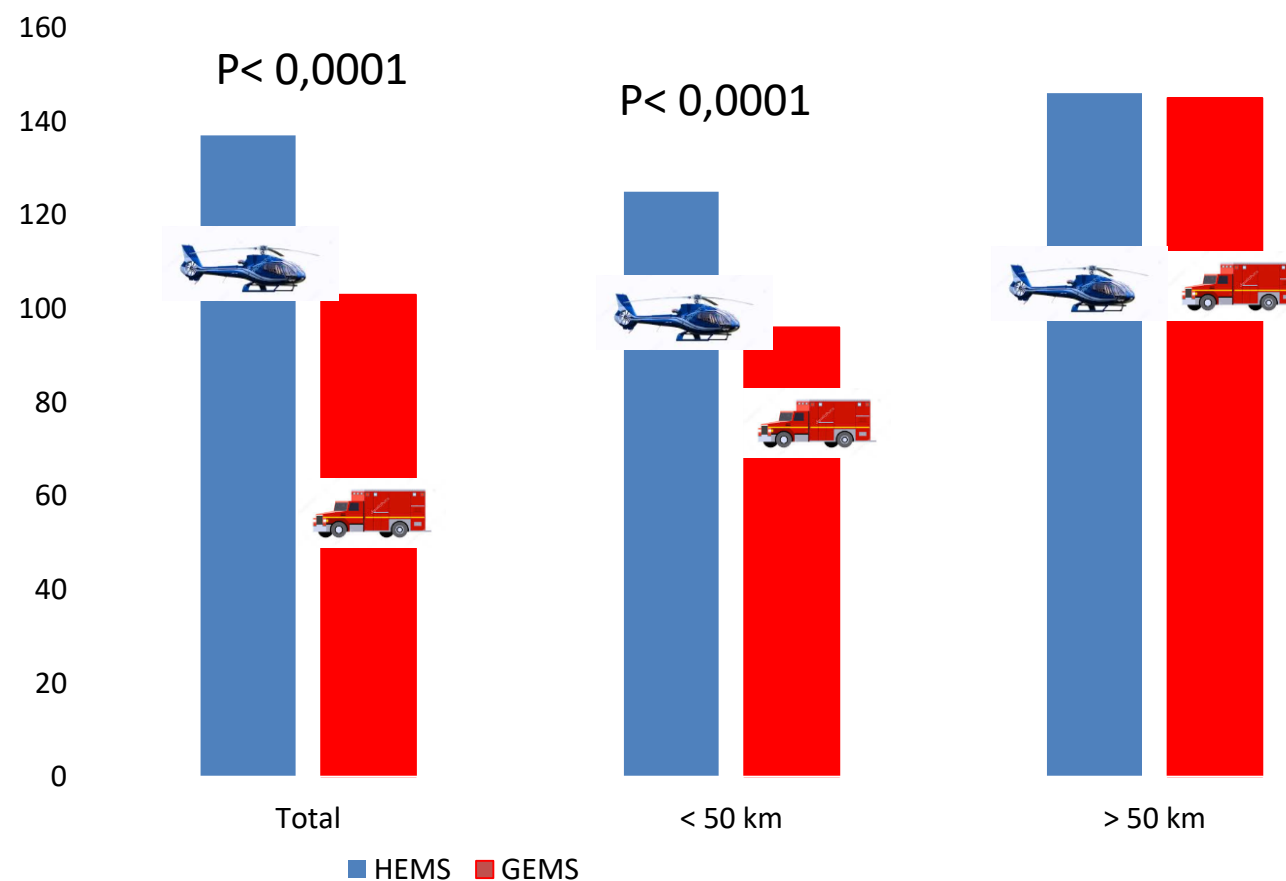


Table 2 Multivariable analysis of factors associated with a first medical contact to primary percutaneous coronary intervention time of > 120 min in patients with ST-segment elevation myocardial infarction (Centre-Val de Loire region, 2014–2016).

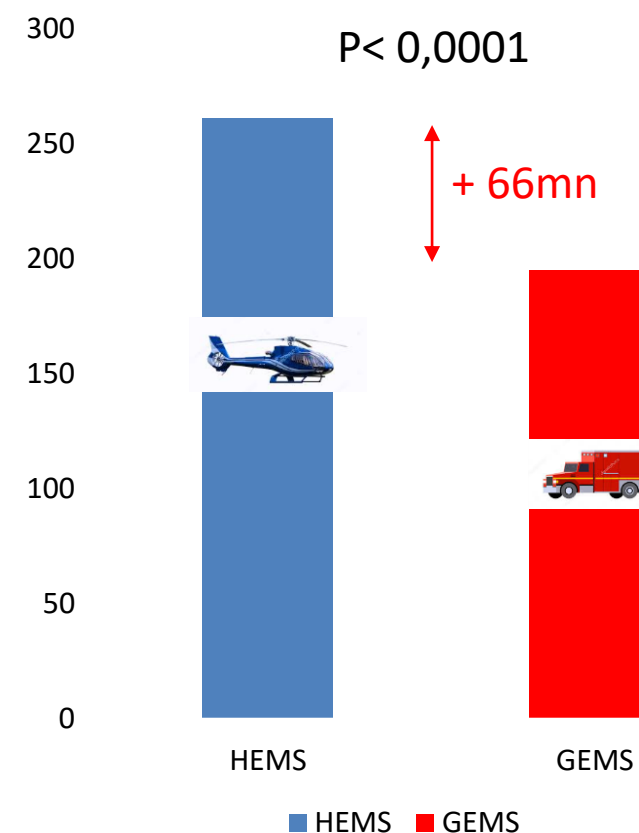
	Multivariable analysis ^a (n = 1938)		
	Adjusted OR	95% CI	P
Age ≥ 65 years	1.2	0.9–1.5	0.15
Female sex	1.2	0.9–1.6	0.22
Diabetes	1.6	1.1–2.2	0.01
Hypertension	1.3	1.01–1.7	0.02
Killip class at admission > 1	1.8	1.3–2.5	0.0003
Site of ischaemia			
Inferior	Reference		
Anterior	1.1	0.8–1.4	0.54
Lateral	1.8	1.1–2.9	0.01
Absence of EMS call	1.6	1.2–2.1	0.001
Time from symptom onset to FMC ≥ 90 min	1.3	1.1–1.7	0.016
Not optimal care pathway ^b	4.5	3.4–6.0	< 0.0001
First admission to hospital without ICC	2.9	2.1–3.9	< 0.0001
Distance from location of onset of pain to ICC			
< 25 km	Reference		
25–50 km	2.2	1.7–2.9	< 0.0001
50–75 km	5.1	3.6–7.0	< 0.0001
≥ 75 km	7.9	4.4–14.0	< 0.0001

HEMS or GEMS for STEMI patients in the overall population

FMC-PPCI delay (mn)



Onset-PPCI delay (mn)



Conclusions

- France PCI is a national registry of IC
 - Steered by interventional cardiologists
 - Already operational in 3 régions (13 centres and soon 30 centers)
 - With high quality of data
 - « Low cost »
 - Supported by all IC protagonists
- 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



ACCUEIL

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Coordonnées

Siège Social du CRAC:

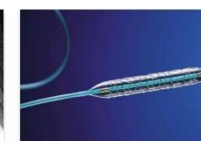
7 Rue Jules Moinaux

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



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

2
9



France – PCI (Business Plan)

100 % Institutionnal Funding

Health administration and regional agency



RESSOURCES HUMAINES ETP = Equivalent Temps Plein	2016	2017	2018	2019	2020	2021 +
Nb régions actives (I)	4	8	12	16	22	22
Nb centres actifs	40	80	120	160	200	200
1- Personnel Equipe Projet (II) ARO : Academic Research Organisation						
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
Total personnel ARO = 6,4 ETP	241,9	289,9	337,9	385,9	433,9	433,9
2- Personnel ARC = Attache TEC = Technicien	Total cost = 3710 k€ /an					
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
Total personnel Régions et Centres = 80 ETP	637,4	1 274,9	1 912,3	2 549,8	3 275,5	3 275,5
Total personnel ARO + Régions + Centres	879,4	1 564,8	2 250,2	2 935,7	3 709,4	3 709,4