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Registry based randomized clinical trial

Dutch
CardioVascular
Alliance

Goal

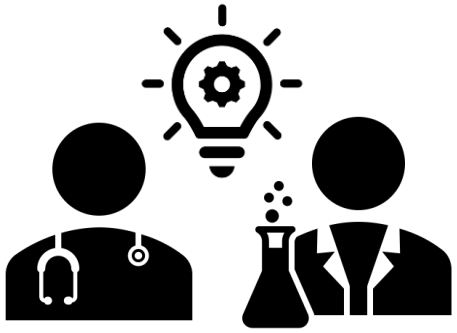
How to create support base for registry-based randomized clinical trials to investigate the effectivity of (novel) therapeutic strategies in daily practice

Why?

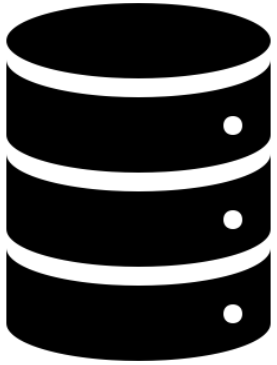
- Classic RCT expensive
- Underrepresentation of specific patients
- Not representative for daily practice
- Limited number of patients because of restricted budget

Registry-based randomized clinical trials

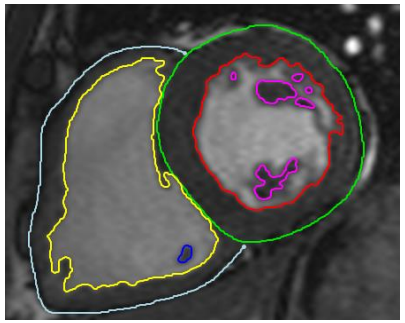
1. Scientist has novel aplication/strategy



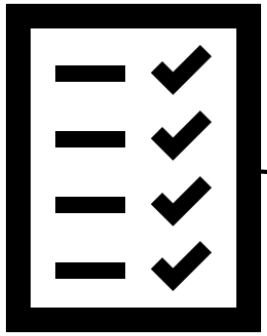
2. Database of all (heart failure) patients



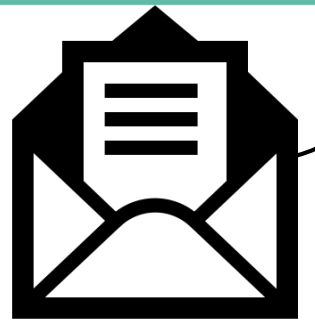
3. Selection of right patients (LVEF)



4. De-anonimize patients to contact

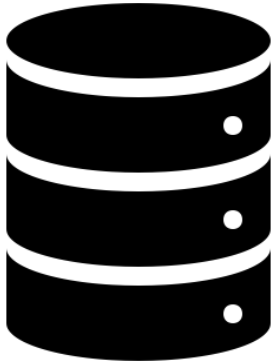


5. Send PIF + IC to patients

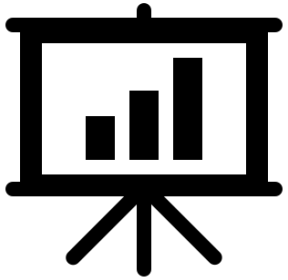


6. Randomize patients to treatment groups

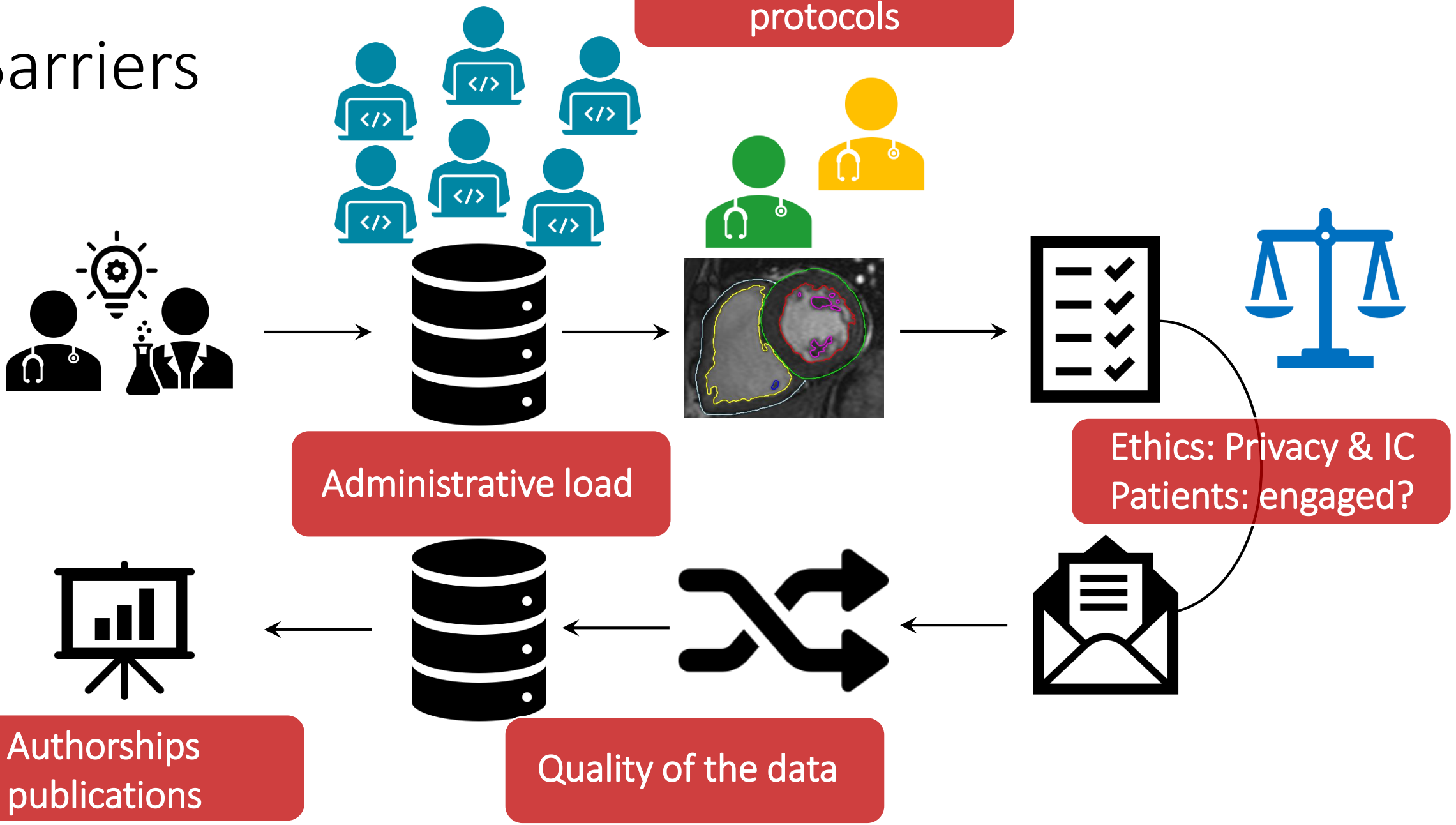
7. Obtain outcome data from clinical care / EMR



8. Analyse efficacy of aplication/strategy



Barriers


Harmonization of protocols
Administrative load
Ethics: Privacy & IC
Patients: engaged?
Quality of the data
Authorships publications



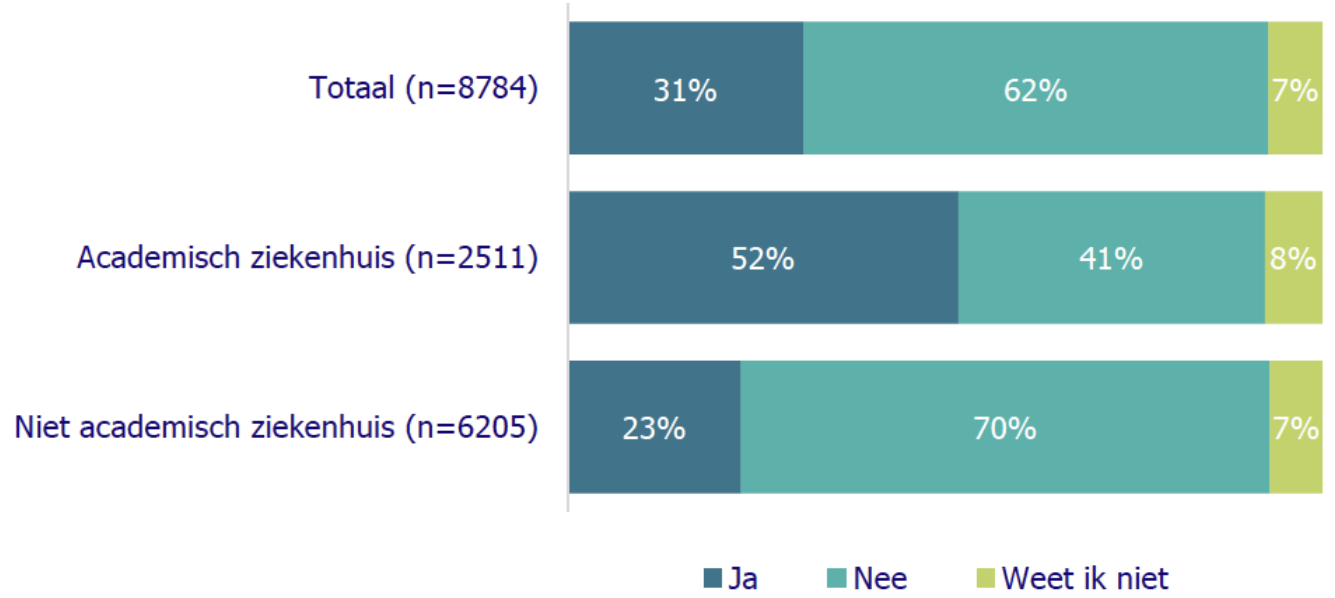



Expert opinions:

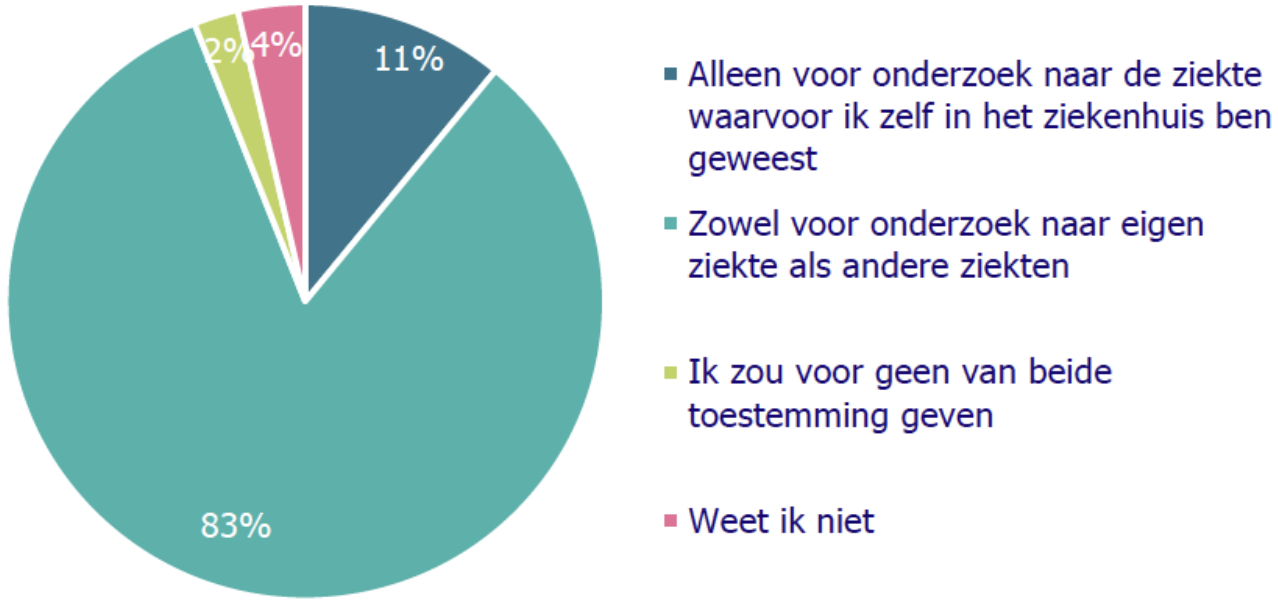
- *'make it feasible'*
- *'data is from/for everybody'*
- *'incoorperation in guidelines is a must'*
- *'transparancy'*
- *'long term plan'*
- *'empower patients'*
- *'broad consent'*

Patient perspective

Bij bezoek aan ziekenhuis wel eens gevraagd om toestemming voor het gebruiken van medische gegevens of lichaamsmateriaal voor medisch-wetenschappelijk onderzoek?



Voor welk doel zou jij toestemming geven? (n=12343)



Bron: *Rapport delen van data in de Gezondheidszorg*. Patientenfederatie Nederland 2021

Key-solutions to generate support-base

Administrative load

- Sufficient, not superfluous, data in clinical care pathways
- Natural language processing, smart queries to alleviate
- Dashboards of clinical care for feedback

ICT, soft- &hardware

- Link multiple registries, databases
- Centralized solutions for ICT-challenges
- Centralized data definitions
- Personnel

Regulatory

- Shared vision! By care professionals, ICT-dept, hospital boards and government
- Reimbursement

Ethics: Privacy & IC

- Informed consent for observational data (@ first contact)
- Specific additional PIF and IC for RBRCTs
- Data safety and GDPR-adherence

Trial & Academics

- Intelligent trial design (data should be present in registry)
- Agreements on authorships and academic rewards

Way forward

'If you want to go fast, go alone

If you want to go far, go together'

African proverb