Red de Salud Materno Infantil y del Desarrollo.

"Una manera de hacer Europa"

PROPUESTAS PARA INICATIVAS CONJUNTAS

Los retos de realizar grandes trials sobre adaptación circulatoria neonatal

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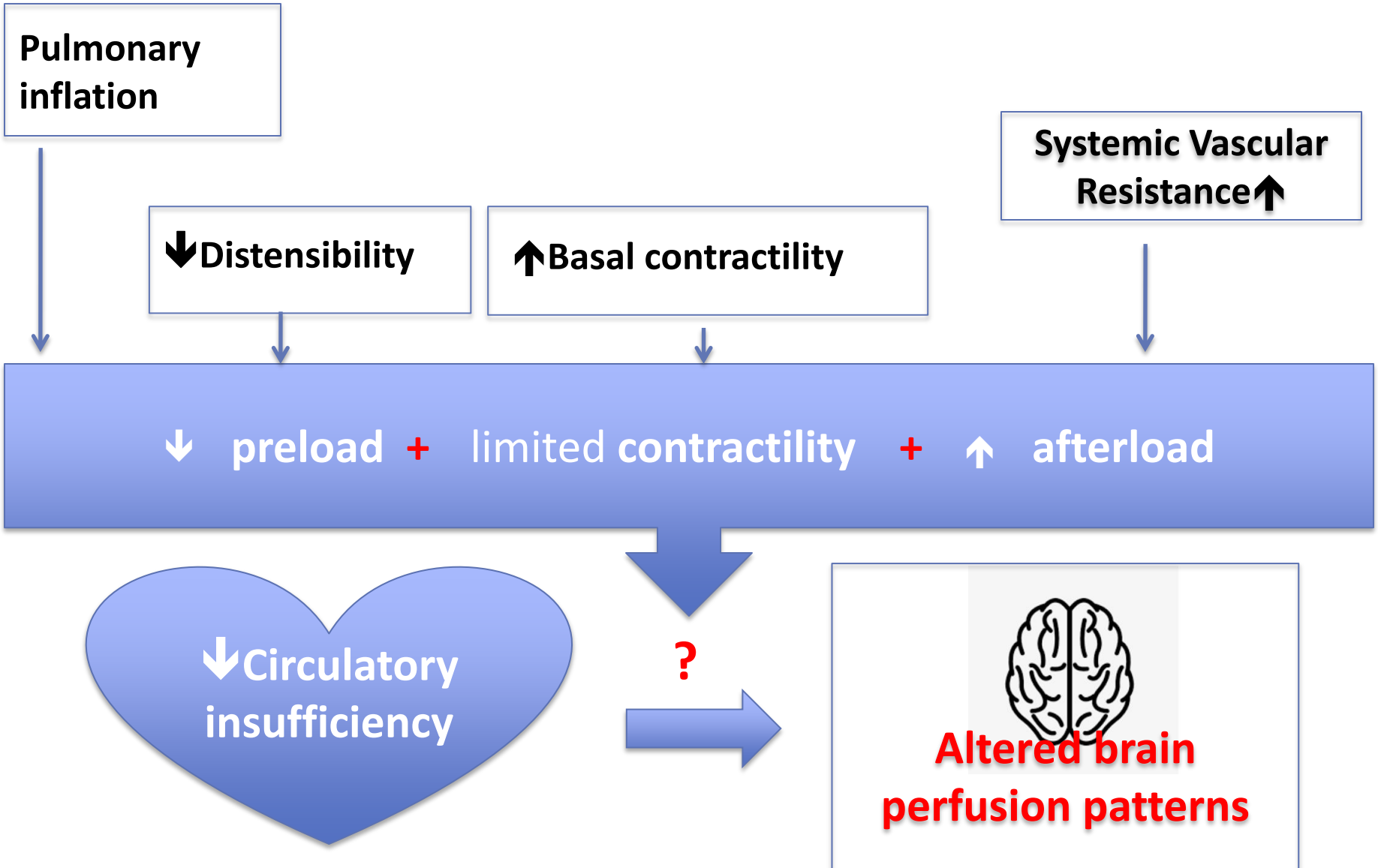
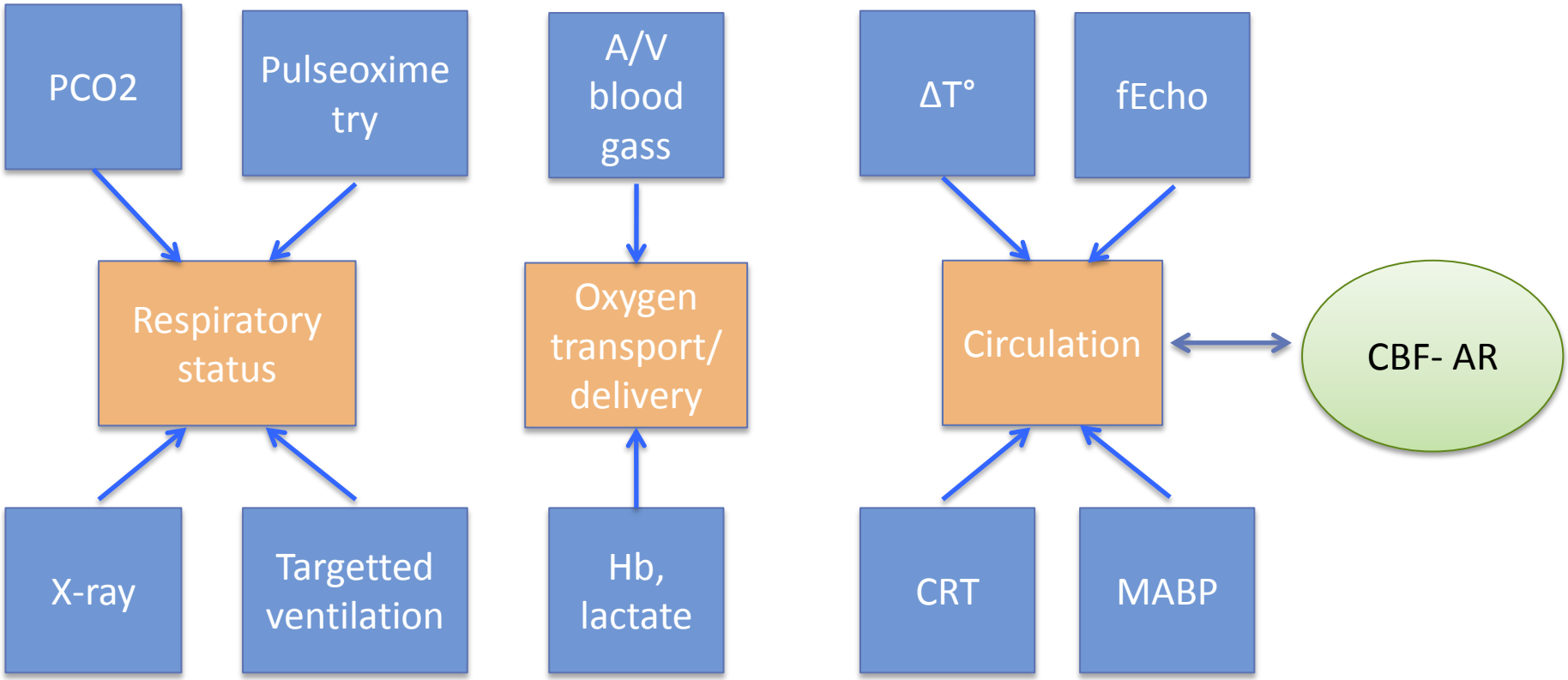
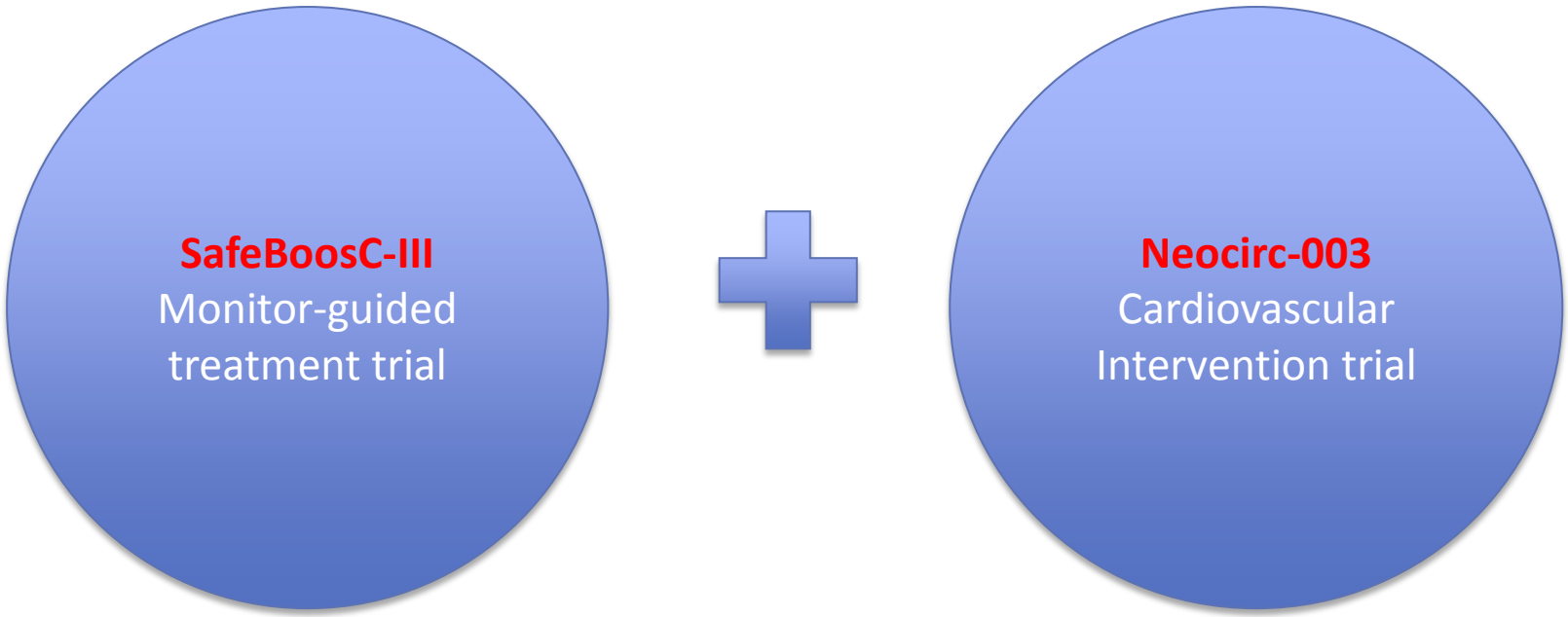
TRANSITIONAL CIRCULATION



THE PATHOPHYSIOLOGY

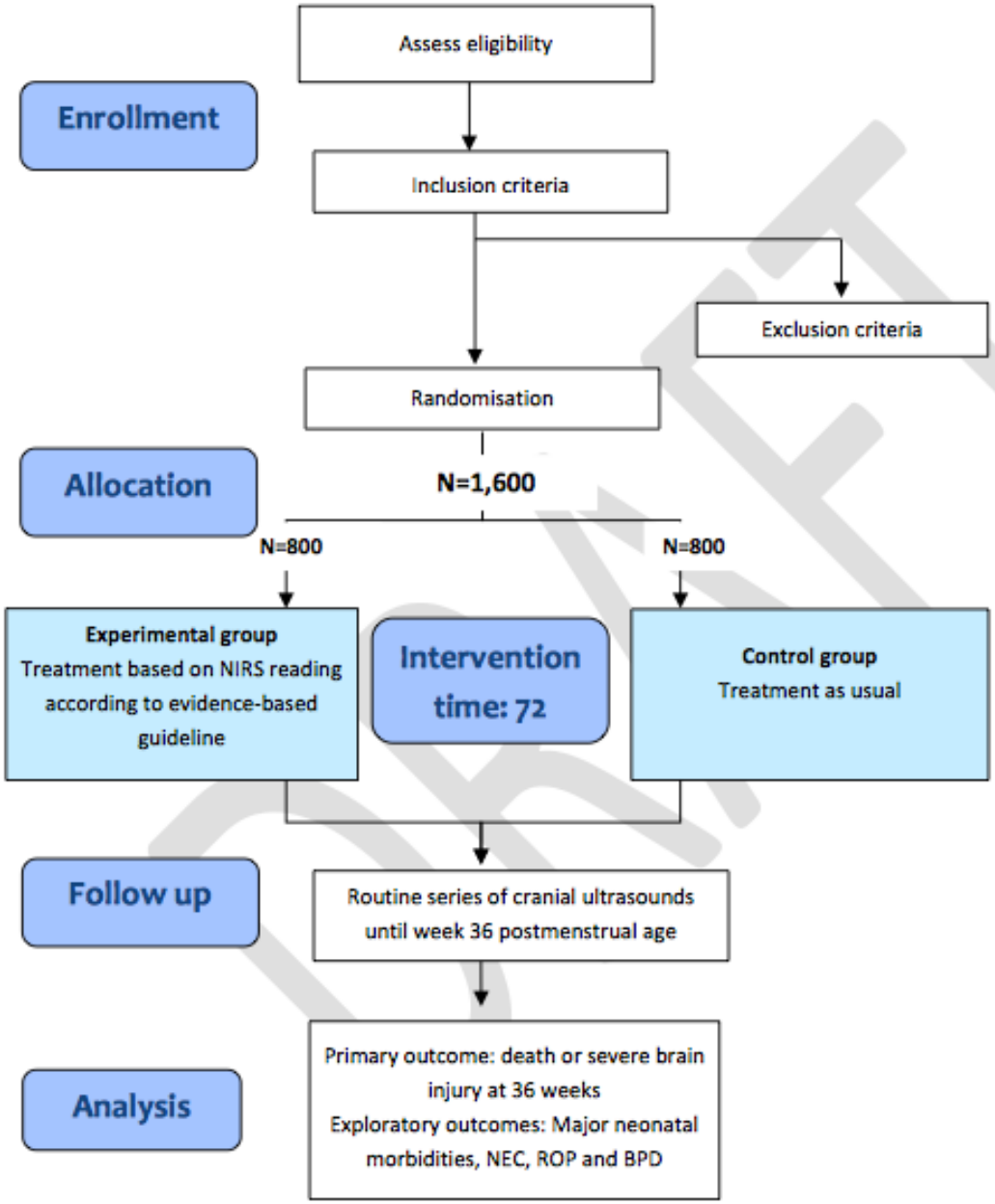


Getting infants into both RCTs

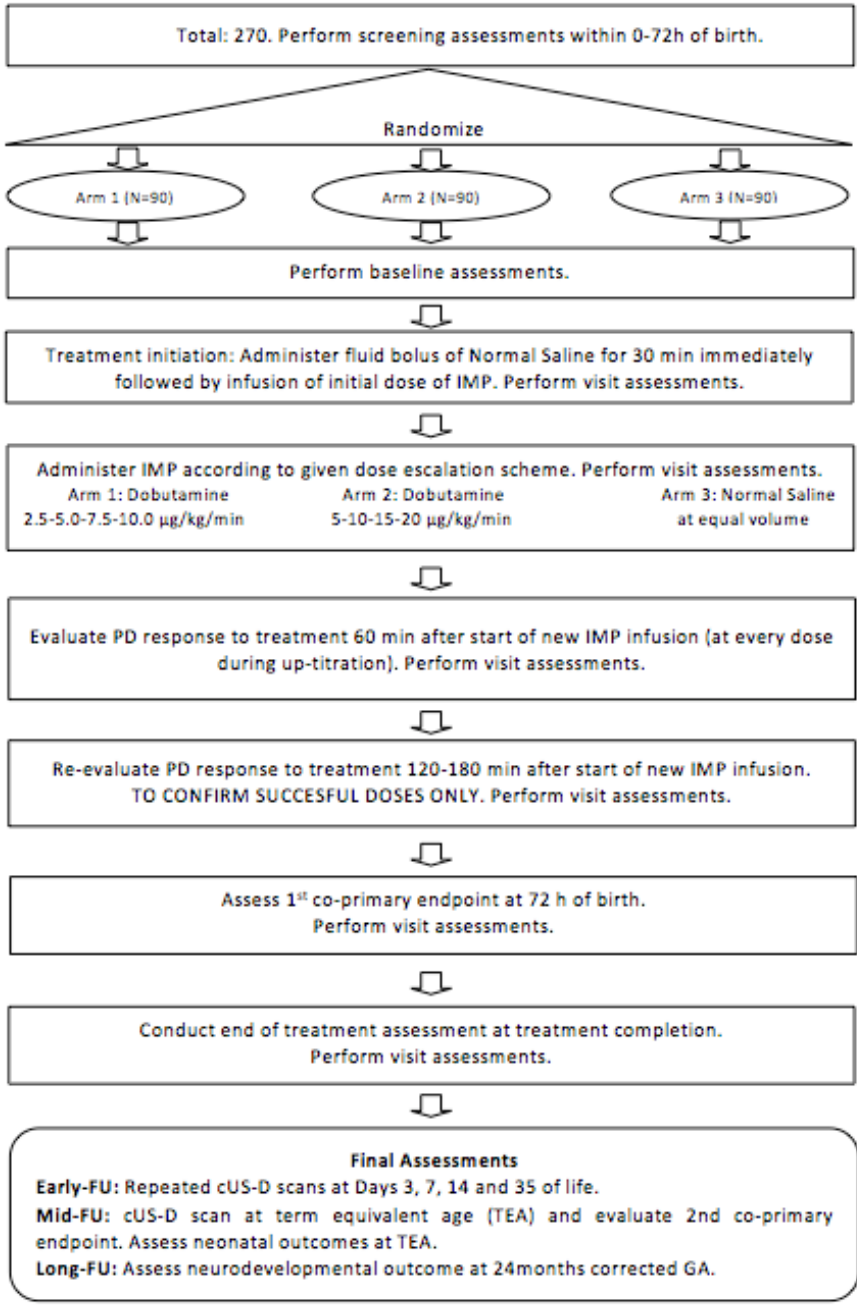


Questions to address have common pathophysiology

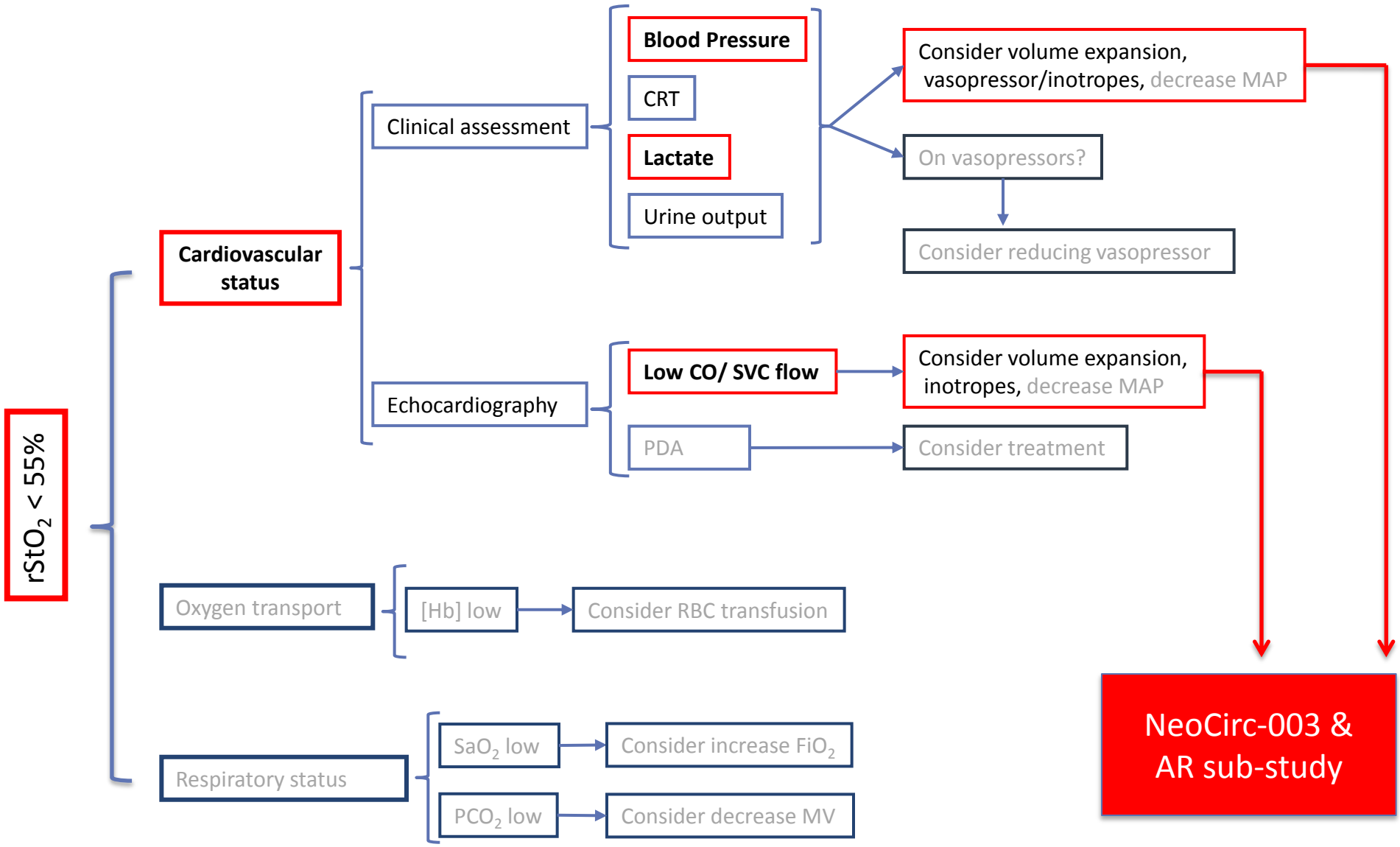
SafeBoosC phase III trial



NeoCirc-003



Clinical intervention algorithm in the SafeBoosC phase III trial

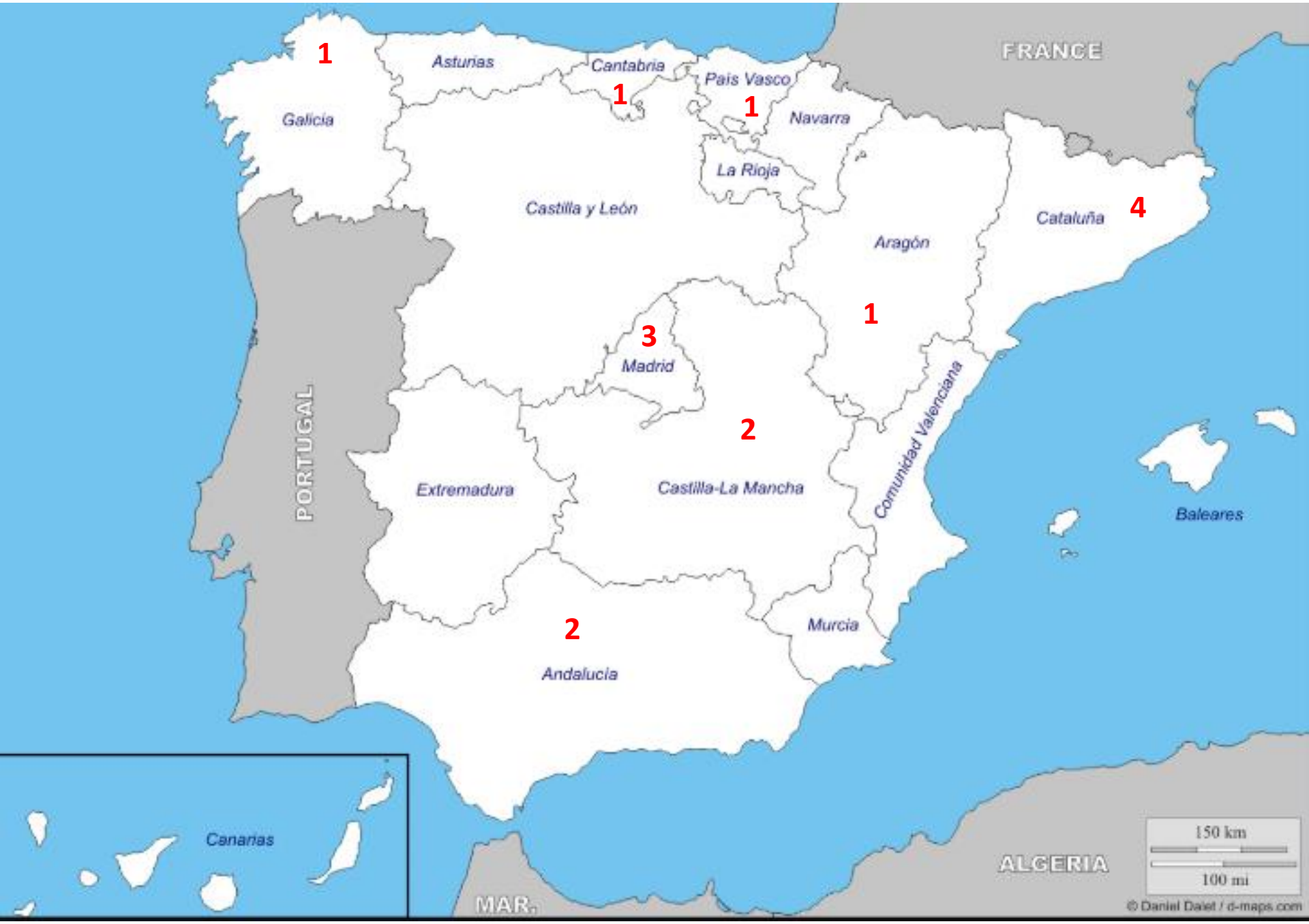


NeoCirculation & CBF-AR sub-studies

- NIRS continuous monitoring
  - Continuos data recording
  - AR studies (invasive blood pressure required)
    - BiAR-COH
    - PDC $_{MABP>>>rStO2}$
  - rStO2 is not a criterion for entry or rescue
  - rStO2 may help in decision-making

Procedures

- Antenatal informed consent
  - Specific ICF
    - SafeBoosC-III (op-out IC/deferred IC)
    - NeoCirc-003 (deferred ICF)
  - Deferred consent in both trials (approval site-dependent)
- CBF-AR only if SafeBoosC-III experimental group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