



# DESIGNING & COMPLETING EFFICIENT RANDOMIZED CONTROLLED TRIALS

PRAPA KANAGARATNAM


TUES 9<sup>TH</sup> OCT HALL 6B

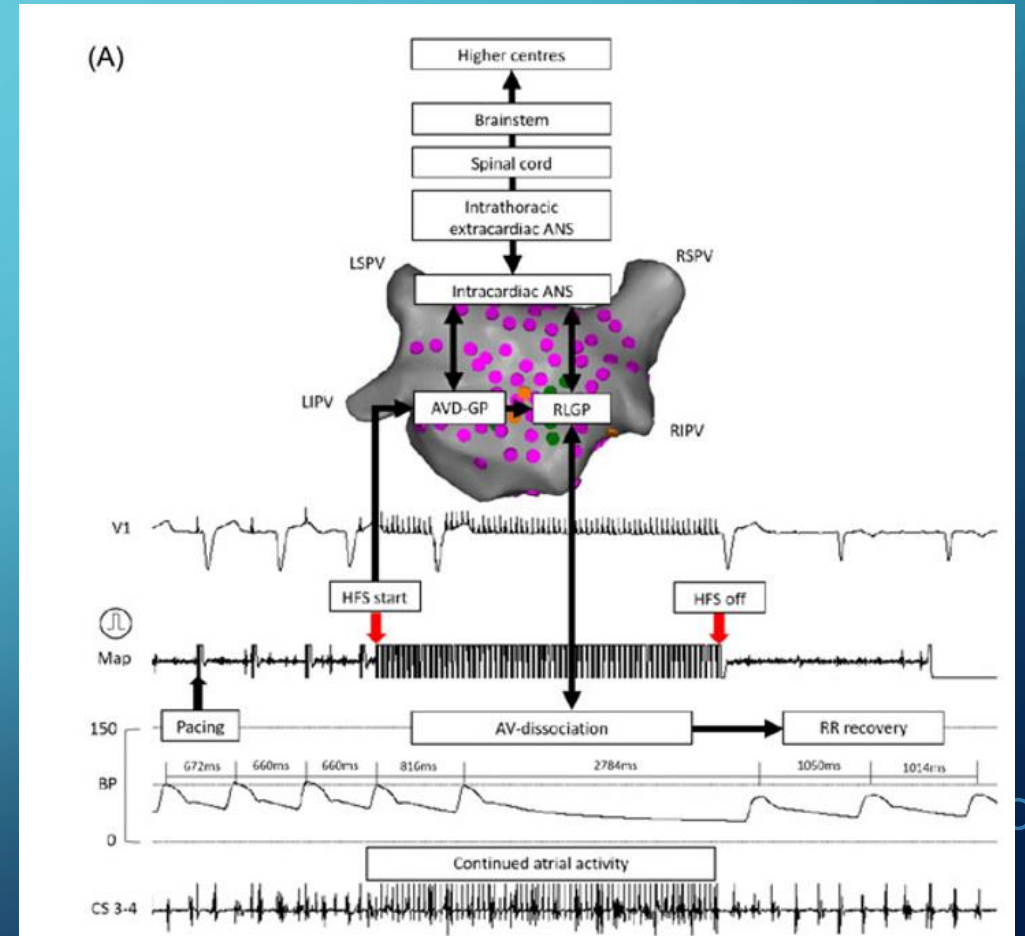
# A BHRS MULTI-CENTRE GROUP PUBLICATION

ORIGINAL ARTICLE

WIL

## A novel approach to mapping the atrial ganglionated plexus network by generating a distribution probability atlas

Min-Young Kim MRCP<sup>1,2</sup>  | Markus B. Sikkel PhD<sup>1,2,3</sup> | Ross J. Hunter PhD<sup>4</sup> |  
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Rheeda L. Ali PhD<sup>1,2</sup> | Chris D. Cantwell PhD<sup>1,2</sup> | Hanney Gonna MRCP<sup>1,2</sup> |  
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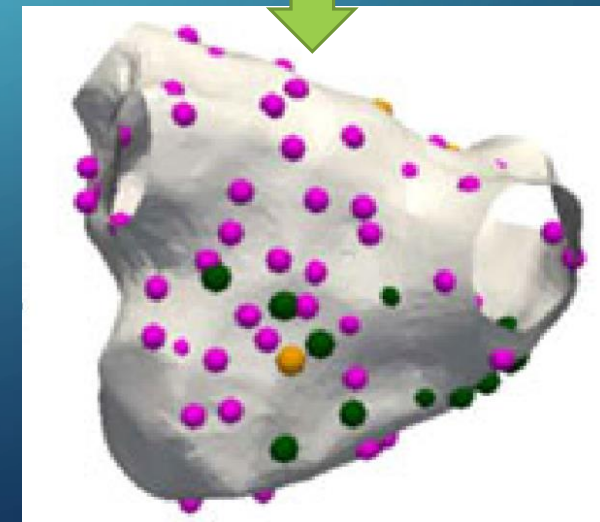
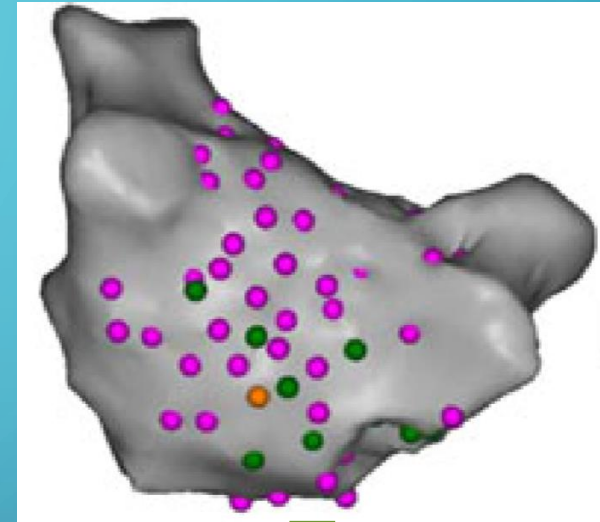
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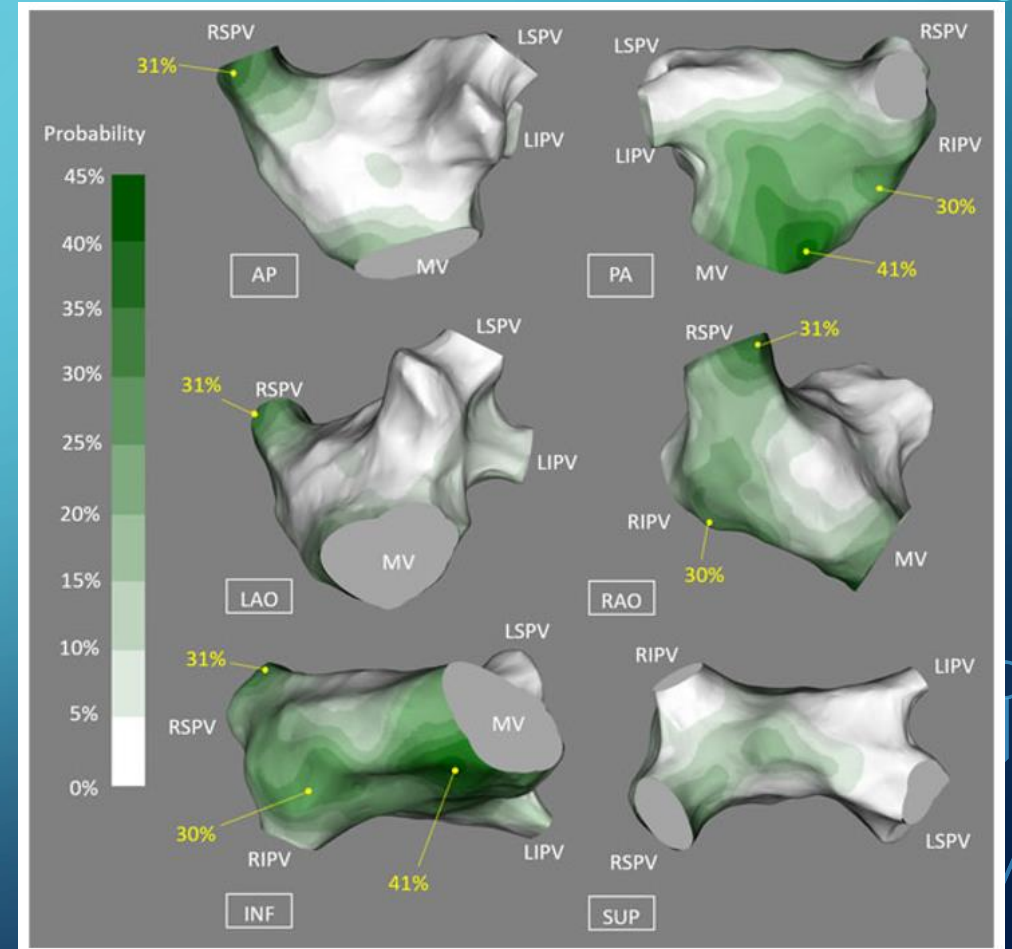
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# PROSPECTIVE MULTI-CENTRE TRIAL EXPERIENCE

## AVATAR-AF

Cryo-PVI without mapping vs standard cryo vs medical therapy

Target 321 pts recruited, FU complete

13 centres, UK

Results will be published 2019

Imperial College Trial Unit

BHF+Medtronic - £650K

## RIPPLE-AT

Ripple vs LAT mapping for AT ablation

Target 110pts recruited, acute study only

5UK + Lisbon

Results will be published APHRS next week

No Trials unit

Biosense -£80K

## ERASE-VT

Robotic VT substrate ablation vs medical therapy

Target 10 European centres ---> 3 centres

Target 200pts ->50pts

Terminated due to Hansen Medical administration

Imperial College Trial Unit withdrew due to slow recruitment

Struggling to publish due to perceived underpowering

Hansen Medical 300K ->100K

# PLANNING THE STUDY

HYPOTHESIS

NUMBER OF PATIENTS REQUIRED TO PRODUCE ADEQUATE EVENTS

HOW MANY CENTRES WOULD BE ABLE/PREPARED TO DO PROTOCOL

RECRUITMENT & FOLLOW UP TIMESCALE

IS IT FEASIBLE?

ARE YOU COMMITTED TO IT?

SCALE OF INTEREST IN OUTCOME/  
SCALE OF PROBLEM

IS A TRIALS UNIT REQUIRED?  
BLINDING REQUIRED

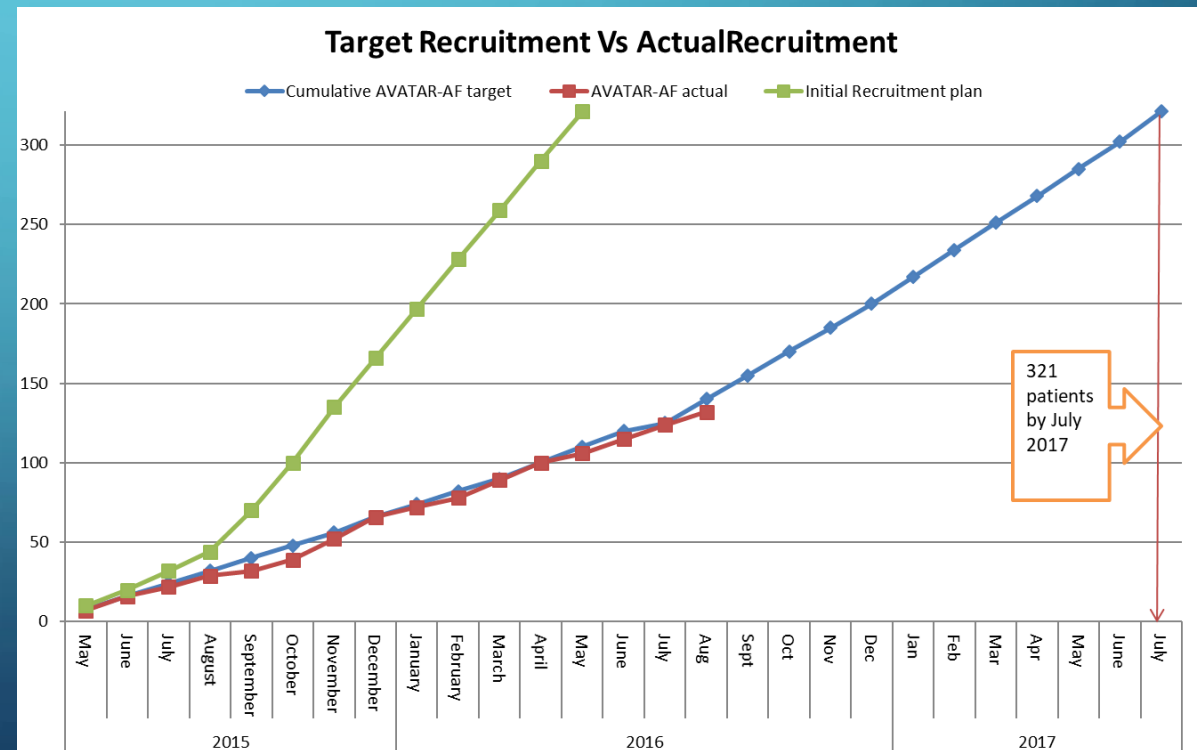
COST

FUNDING CHARITABLE BODIES VS INDUSTRY

PORTFOLIO

# RECRUITMENT

- Do not underestimate how much motivational work is required
- Recruitment plan should be in place early
- Recruitment target chart



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