

# The EmERGE project: the result of a changing disease in a changing world

72<sup>ste</sup> geneeskundige dagen van Antwerpen

Dr. Ludwig Apers

ITG

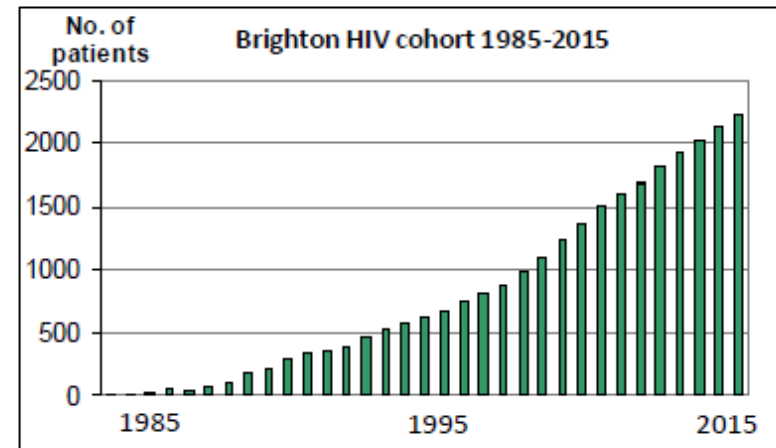
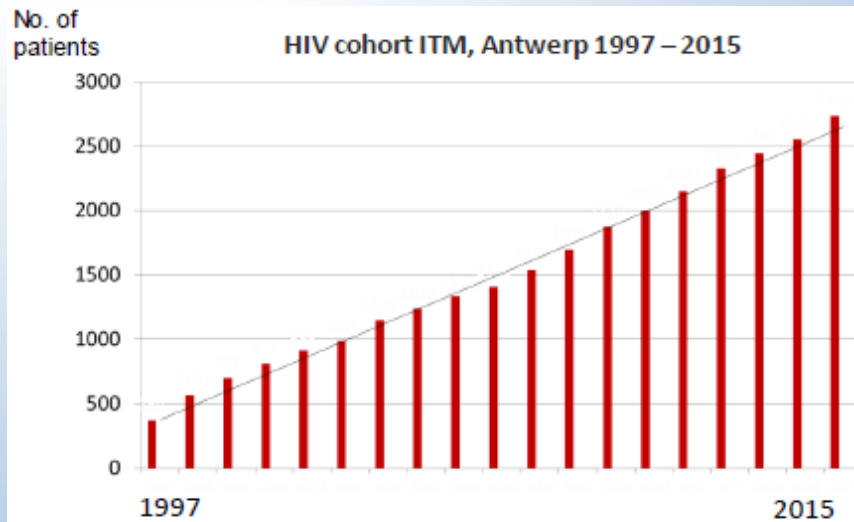


# Overview

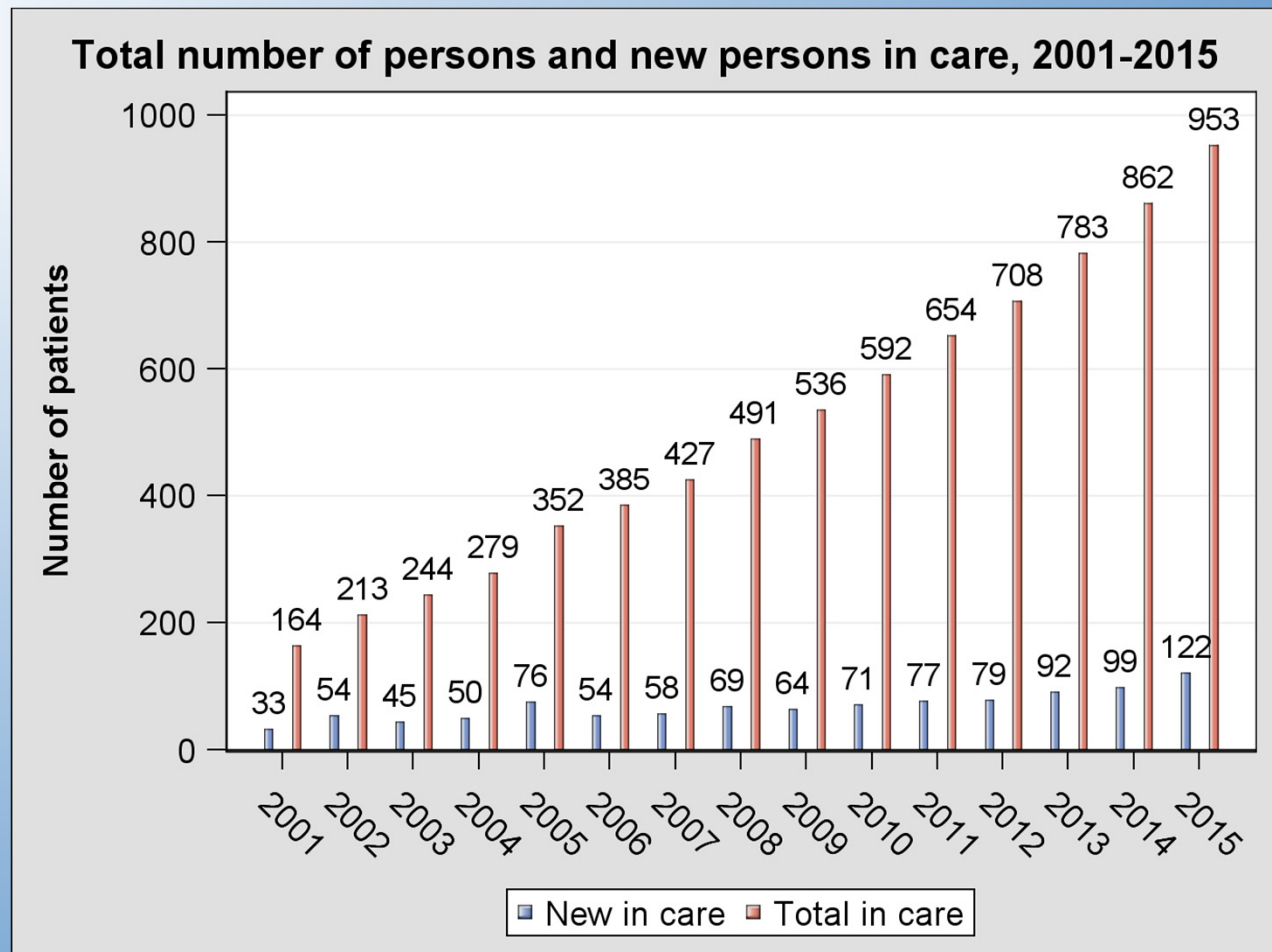
- A changing morbidity and mortality pattern
- Effect on health services organisation
- A changing world
- Possible answers
- EmERGE?
- Validation study: concept
- Preparatory work
- First inclusions



# Prolonged life expectancy, decreased mortality: ever increasing numbers of patients



# Zagreb HIV cohort 2001-2015



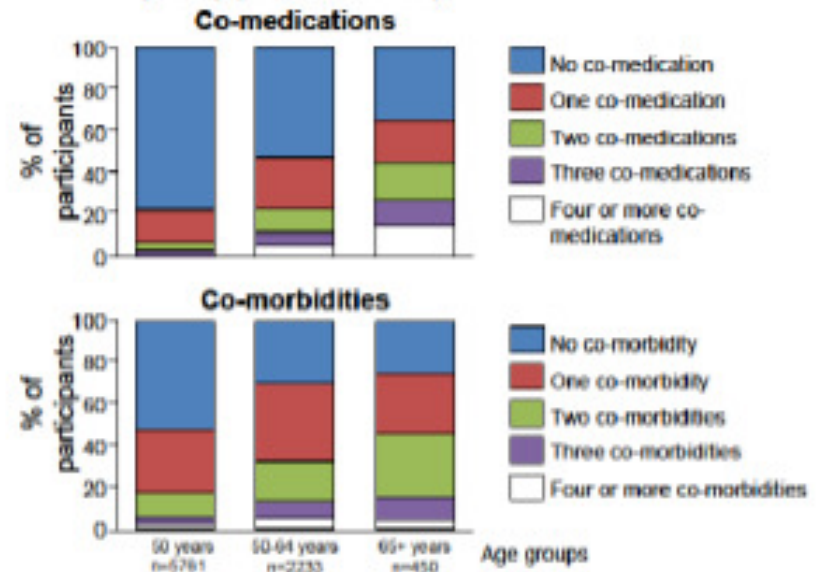
# Ageing and frailty: changing morbidity

Reduced complexity of  
HIV control

Increased number of co-  
morbidities and  
polypharmacy

## Ageing and HIV: co-morbidities and polypharmacy

**Swiss Cohort**  
NB: most patients on  
3 ARVs in addition to  
these medications,  
poly-pharmacy is the  
norm at 50 years.



Hansen B. et al. CID 2011; 53: 1130-1136

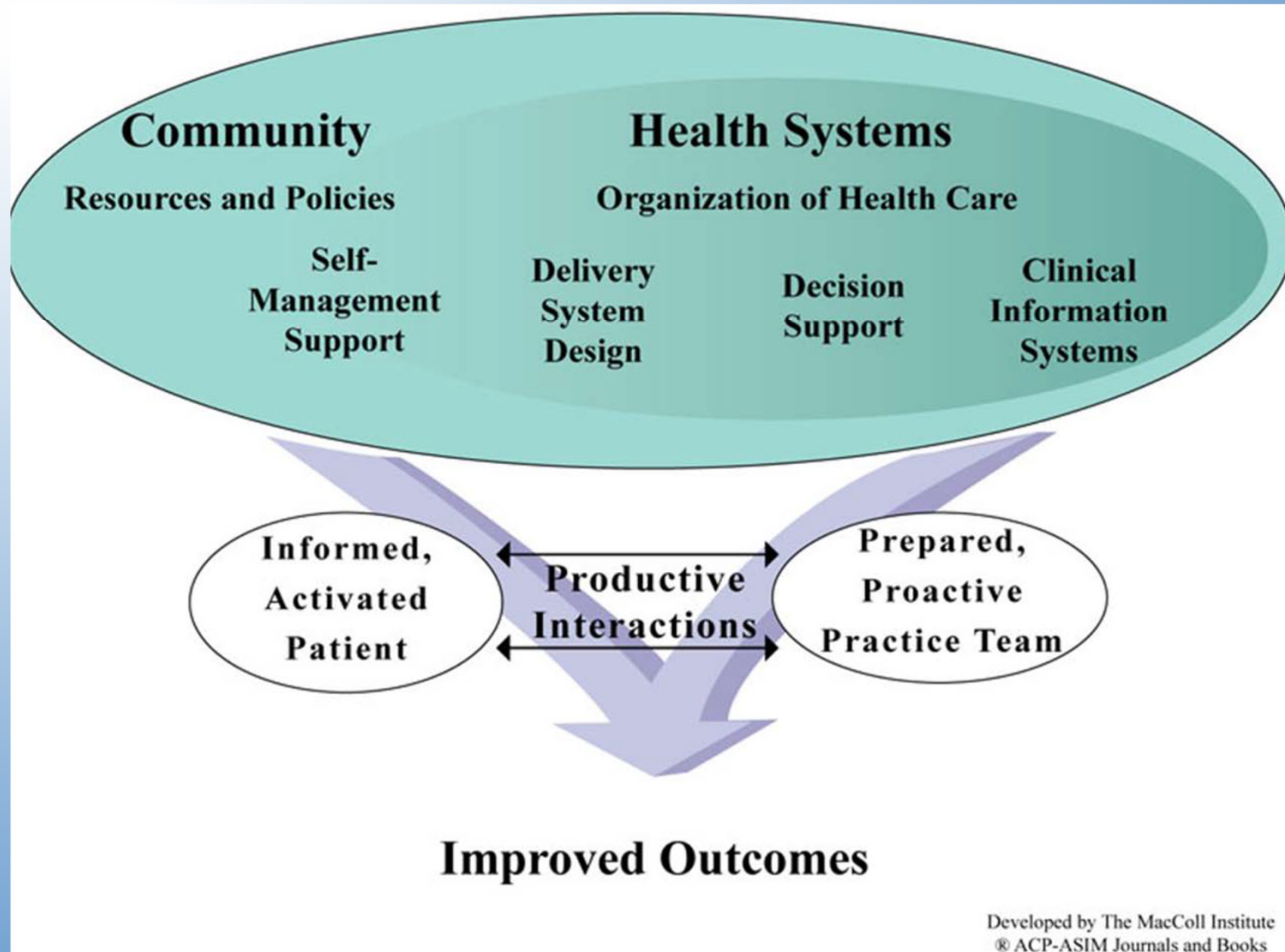


# New 'pathways' to follow-up the stable patient

Huisarts	Aids Referentie Centrum
Opvang van niet-hiv gerelateerde problematiek	Eerste contact: medische en psycho-sociale begeleiding van een HIV diagnose, uitvoeren van relevante 'staging' en screeningsonderzoeken
Preventie: <ul style="list-style-type: none"> <li>• Optimale vaccinatiestatus (incl. griep en pneumovac)</li> <li>• Cardiovasculair risico</li> <li>• Osteoporose</li> <li>• Jaarlijks PAP-smear</li> <li>• Diabetes screening</li> <li>• Rookstopbegeleiding</li> </ul>	Opstart van een anti-retrovirale (ARV) therapie: administratieve, medische en psycho-sociale begeleiding
Evaluatie en begeleiding van therapietrouw	
Soa/hiv-screening van de partner op regelmatige tijdstippen.	Monitoren van immuniteitsstatus en nevenwerkingen
Algemene administratieve begeleiding: werkonbekwaamheid, invaliditeit, ect.	Bepalen van resistentiepatroon en eventuele ARV-aanpassing
Zorgen voor laagdrempelige opvang: derde betaler, oproepen voor afspraak, ect.	Selecteren en begeleiden van patiënten die deelnemen aan klinische studies



# 'the chronic care model' (eg. KCE report 2012)



# Belgian context: action plan e-health - MoH



[www.plan-esante.be](http://www.plan-esante.be)

[www.plan-egezondheid.be](http://www.plan-egezondheid.be)



eGezondheid: voordelen én valkuilen







# **E**valuating **m**Health technology in HIV to improve **E**mpowerment and healthcare utilisation: **R**esearch and Innovation to **G**enerate **E**vidence for personalised care

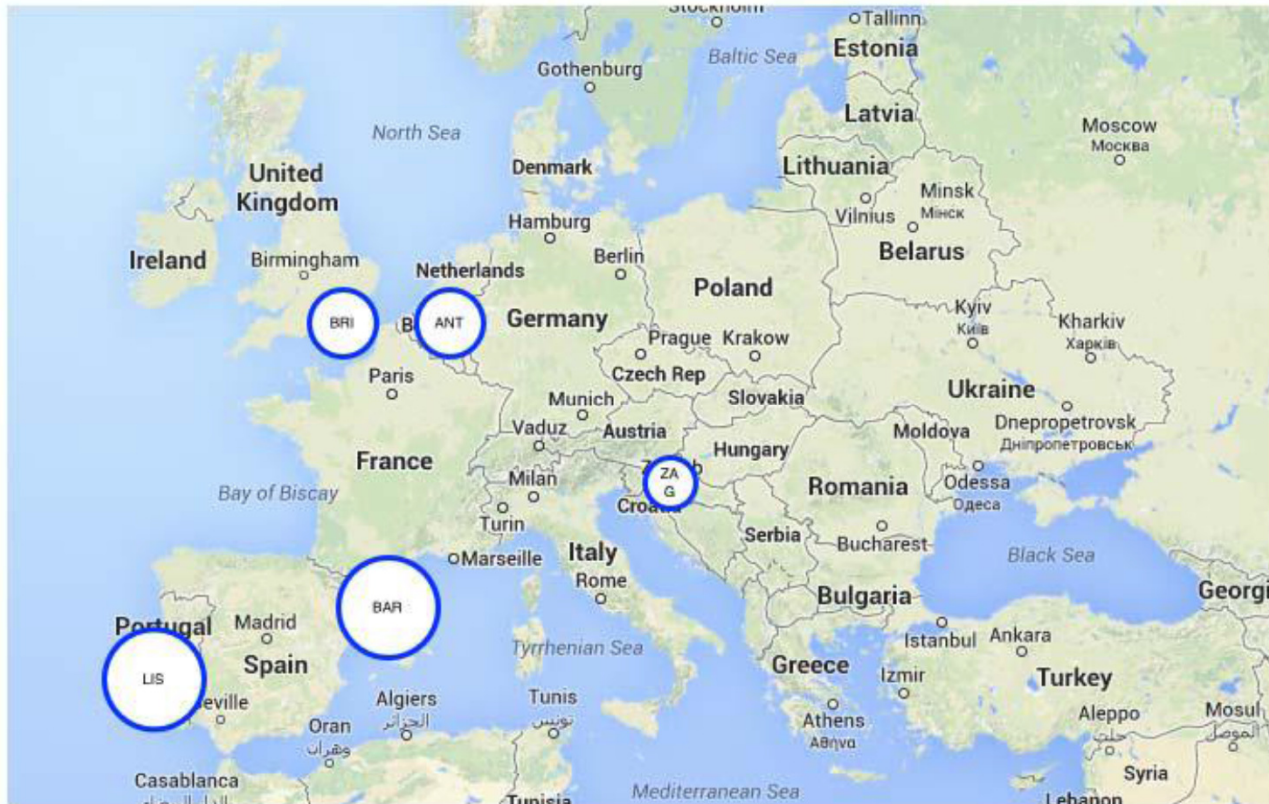
European Union's Horizon H2020 research and  
innovation programme: Grant Agreement No 643736

Five year project: May 2015 - April 2020

This project has received funding from the European Union's Seventh  
Framework Programme for research, technological development and  
demonstration under grant agreement no 602108

Five clinical sites:

- Antwerp
- Brighton
- Barcelona
- Lisbon
- Zagreb



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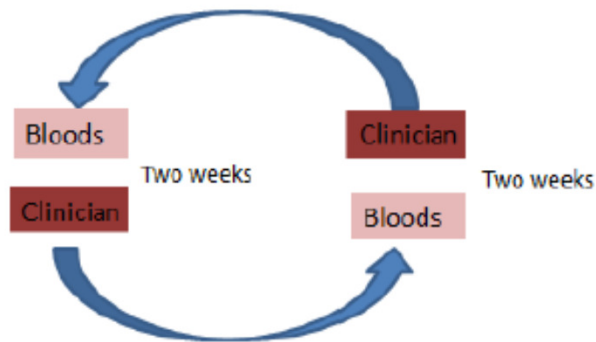
## Objectives

- i. *To develop a novel mHealth platform for use by 3,900 patients with stable HIV infection in five different European settings – platform developed, integrated and piloted by M18*
- ii. *To validate acceptability, usability and effectiveness of the mHealth platform in routine HIV patient clinical management – validation study completed by M54*
- iii. *To assess the impact of the mHealth platform on patient self management and empowerment – study powered to demonstrate improvement in patient empowerment*
- iv. *To analyse cost, cost effectiveness or cost saving associated with installing the mHealth platform in participating health systems – health economic analysis integral part of work plan, completed by M54*
- v. *To valorise the outputs of the work via a consortium centred value chain and business plan to promote and implement the mHealth platform in various European healthcare settings as a sustainable, effective, safe and economic modality for HIV care*

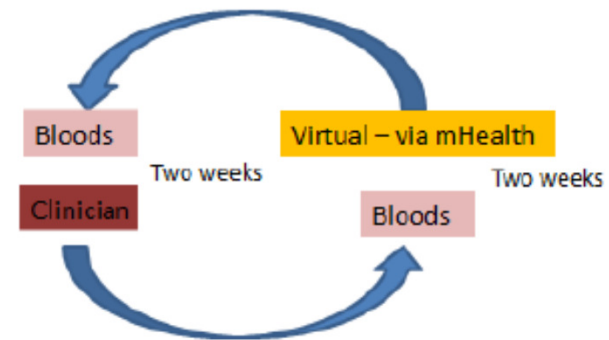


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## Concept



Person living with stable HIV seen twice a year for routine follow-up, usually with blood samples drawn two weeks prior to clinician appointment



Proposed EmERGE pathway – seen routinely once a year with interim visit carried out via mHealth platform

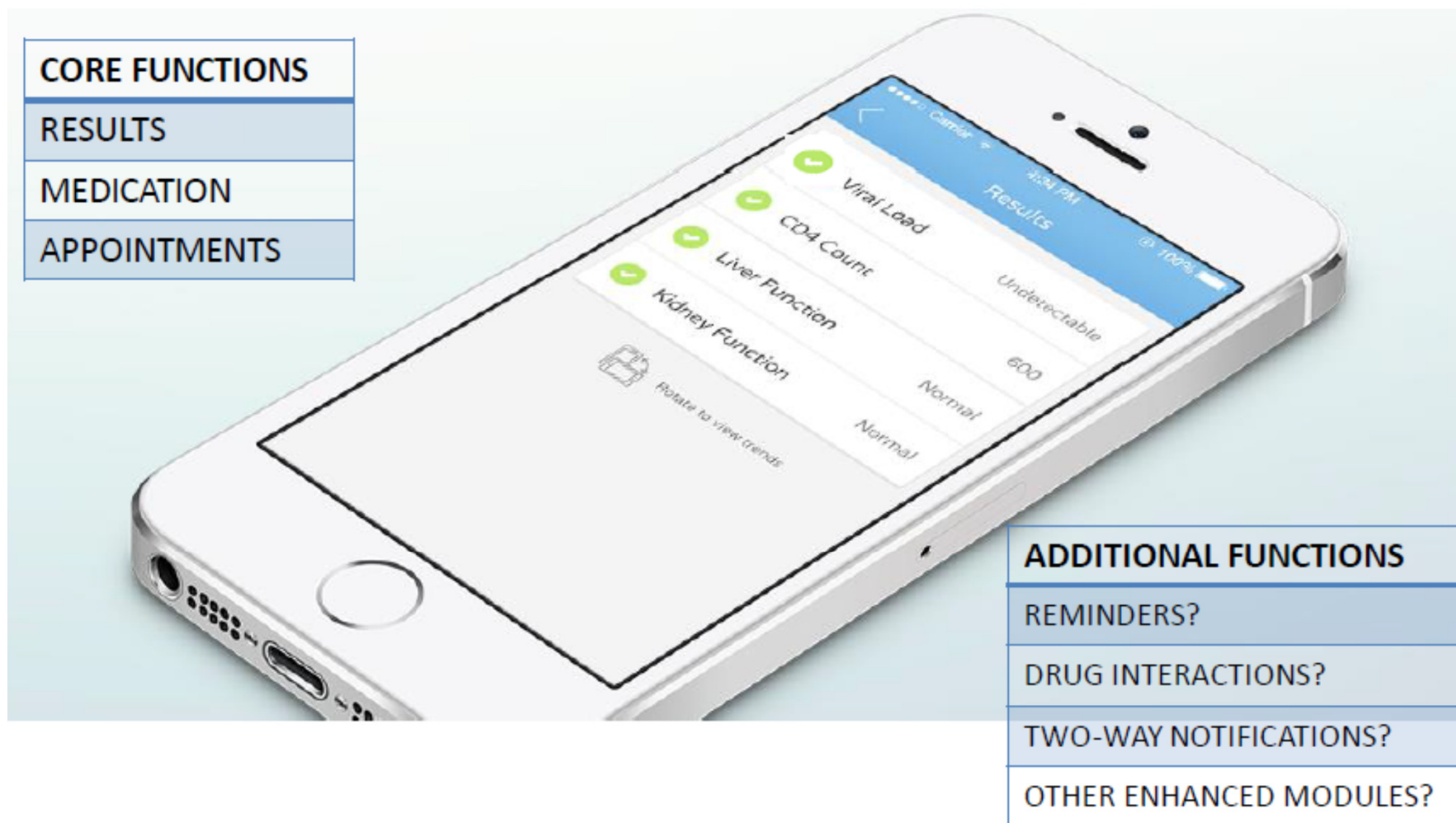
- \*Results checked by a clinician
- \*Pushed through securely to 'App' with medication info & future appt
- \* Prescription issued
- \* Option to pause if any problems



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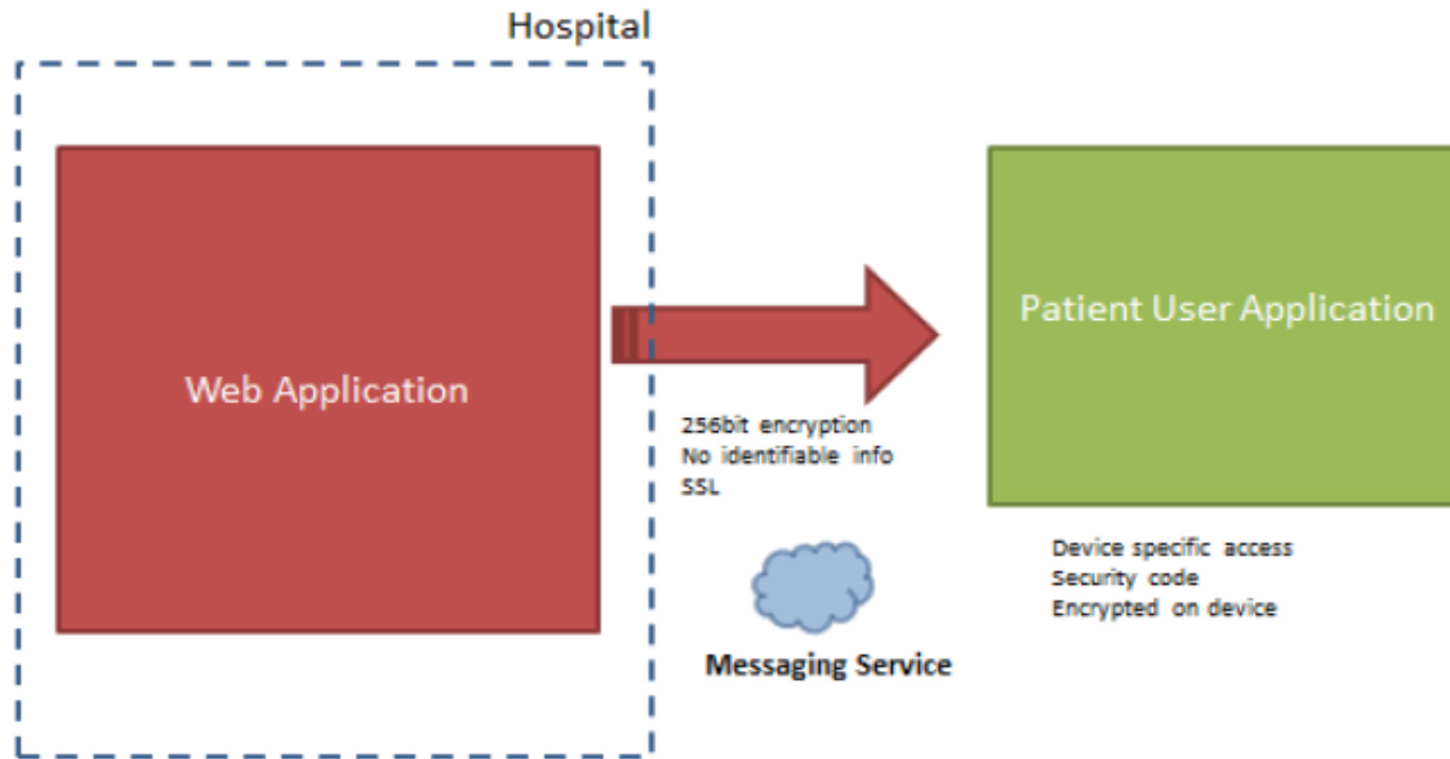


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## Work streams and partners

### **Work stream 1 - Development and integration of the mHealth platform**

WP1 – Situational Analysis and Background Assessment

WP2 - Co-Design and Sociotechnical Evaluation

WP4 – Platform Development, Testing and Deployment

### **Work stream 2 – Validation Study**

WP3 – Health Economics

WP5 - Implementation and validation study

WP6 – Quantitative Patient Outcomes

### **Work stream 3 – Innovation, Exploitation and Dissemination**

WP7 – Innovation and Exploitation

WP8 – Dissemination

WP9 – Project Management



**Institute of Tropical Medicine,  
Antwerp**



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University of Brighton



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**NPMS-HHC,  
London**

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**FCRB, Barcelona**



**BSUH, Brighton**



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# Validation study

A large (3808 patients) prospective cohort study, undertaken in five European sites to validate an mHealth platform to enable self-management of HIV in patients with stable disease using a tailored HTA process, Model for Assessment of Telemedicine Applications (MAST), specifically developed for the assessment of mHealth solutions.

As site recruitment will be sequential and the recruitment period will last 18 months at each site, a maximum follow-up of 35 months will be undertaken. Study visits will take place at baseline defined as the time of mHealth introduction, months 6, 12, 18, 24 and 30.



### INCLUSION CRITERIA

1. Documented HIV positive; Age  $\geq$  18 years of age; Able to give informed consent
4. In possession of a smartphone, tablet, or similar technology supporting the mHealth platform
5. Stable on ART

ART should be unchanged for at least 3 months, and viral load undetectable for at least 6 months.

6. Clinically stable from an HIV perspective

- a) No opportunistic infection within the previous 12 months
- b) No current HIV-related illness requiring ongoing treatment or monitoring

### EXCLUSION CRITERIA:

1. Aged less than 18 years, Pregnant
2. Participating in a clinical trial or receiving an investigational medication
3. Unable to comprehend the patient information sheet; to comprehend the instructions for using the mHealth platform
4. Considered for any other reason by their regular physician to be unsuitable for study participation



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- “The diversity of the study population (varying proportions of MSM, IVDUs, non-nationals, varying sex ratio’s and age distributions) is an asset for the project, as all subgroups will be represented. “





# Work Package 2

## Sociotechnical Evaluation

Flis Henwood, Mary Darking,  
Benjamin Marent & the EATG



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# Study participants: Healthcare professionals

## Overview: Healthcare professionals

N	<ul style="list-style-type: none"><li>• 51</li></ul>
Gender	<ul style="list-style-type: none"><li>• 17 m</li><li>• 34 f</li></ul>
Occupational background	<ul style="list-style-type: none"><li>• 34 physicians</li><li>• 9 nurses</li><li>• 1 sexologist</li><li>• 3 psychologist</li><li>• 1 pharmacist</li><li>• 1 administrative staff</li><li>• 1 IT specialist</li><li>• (1 missing)</li></ul>



## Substitution of face-to-face visit

- Several clinicians highlighted that information and advice for patients is constructed in dialogue and also based on physical examination of the patient
- Many PLWH stated that they want to see their HIV clinician at least every 6 months; they emphasized that in this consultation they can discuss also emotional and social aspects related to HIV
- Therefore, several participants argued that patients should have the option whether they want a face-to-face visit or manage their health via an app





**EmERGE validation study WP5    Newsletter 5 - 01- September-17**

Dear EmERGE members,

We are pleased to send you the fifth Newsletter for the EmERGE validation study WP5.

Site	Nº Recruited patients	Nº Patients completed baseline	Nº Patients completed M12	Nº Patients completed M24	Nº Patient withdrawn	Completed visits on eCRF %	Nº Finalized patients
Brighton	142	142	0	0	0	0	0
Zagreb	143	143	0	0	0	0	0
Barcelona	16	16	0	0	0	0	0
Antwerp	1	1	0	0	0	0	0
Lisbon	Pending Integration						





... work in progress...

# Thank you



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