HEAD* Start Georgia; projects overview

*** Hepatitis C Elimination through Access to Diagnostics**

Sonjelle Shilton

FIND, HCV/HIV Project Manager

HEAD-Start projects overview

FIND began discussions with NCDC regarding support to HCV program in 2016.

From that time joint projects include:

Completed

- FIND clinical evaluation on Xpert® Fingerstick HCV cartridge in cooperation with Lugar center and Hepa+
  - 310 persons provided with confirmatory testing

Ongoing

- HEAD Start decentralization of HCV diagnostics study
- HCV Rapid Diagnostic Test (RDT) evaluation

In preparation

- HCV core antigen as test of cure study
- HCV DBS validation study
- HCV Genedrive study of use in intended settings
- Catalyzing scale up of decentralization of diagnosis

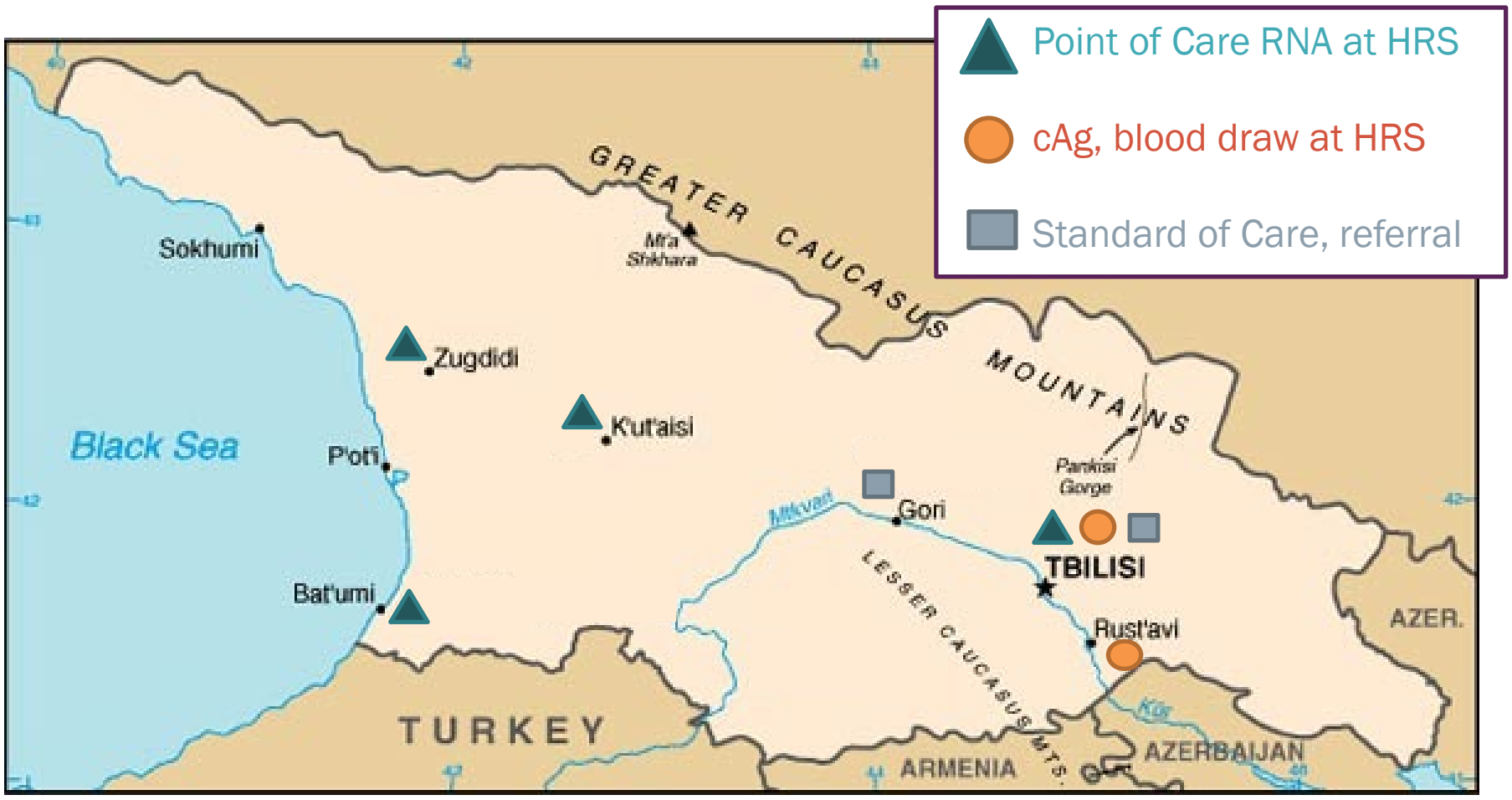
HEAD Start decentralization of diagnostics study

HEAD-Start decentralization of diagnostics study in Georgia

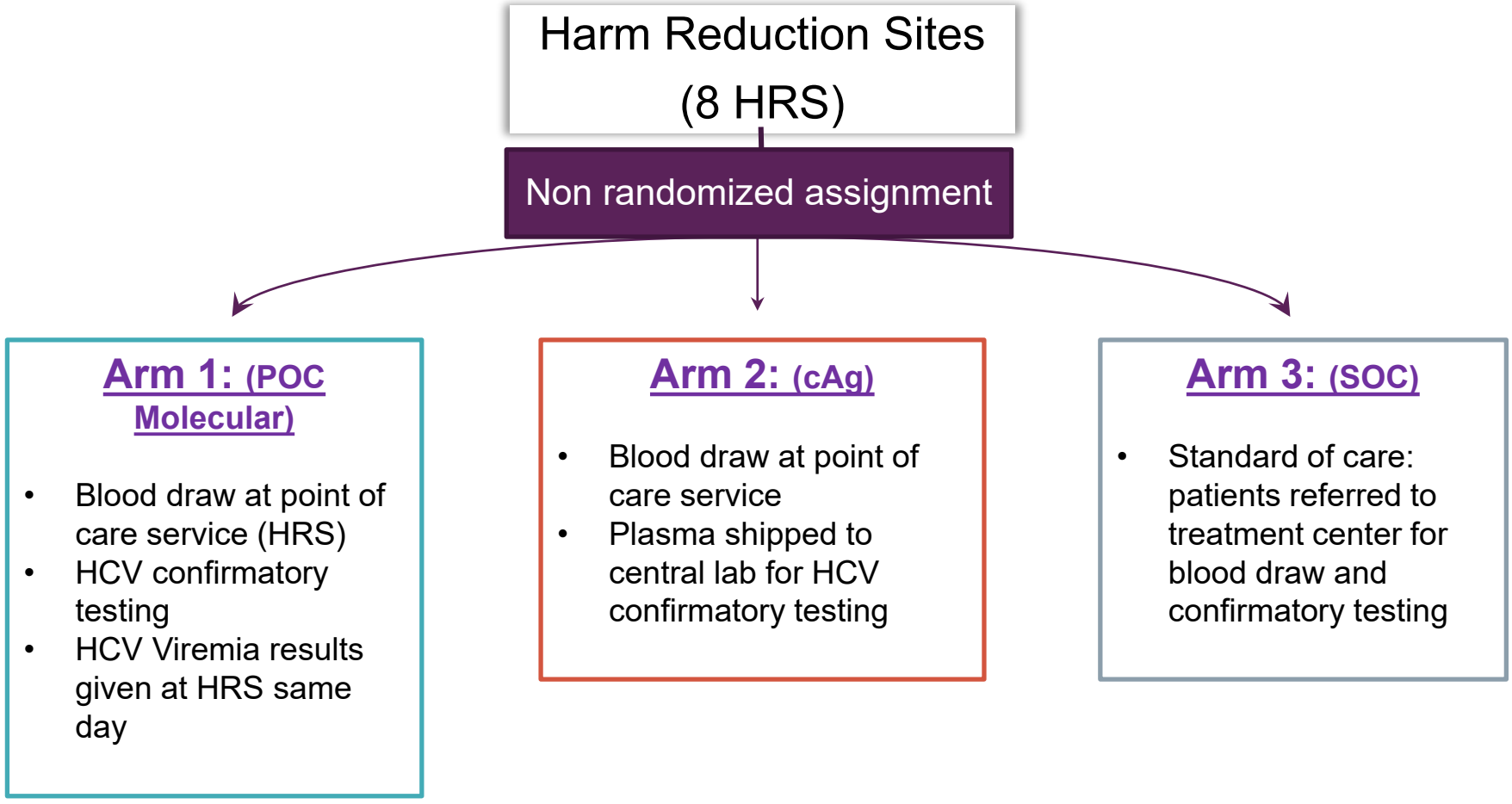
Objective:

To determine whether the proportion of participants who receive results of HCV viremia testing differs between Harm Reduction Site (HRS) based testing (either decentralized HCV RNA testing, or blood draw at HRS for centralized HCV cAg testing) and referral-based testing [standard of care (SOC)] among PWID who test anti-HCV-positive at HRS.

HRS sites included in study



Study design



Study sample size

Total to be enrolled: 1860 HCV RDT+

FIND is covering the costs for all associated diagnostic tests and doctors visits during treatment of the enrolled participants

Study timeline

Initial Georgian IRB approval June 2017 - HRU, Sep 2017 - NCDC

Arm 2 and 3 study training Feb 2018

Unitaid Human Subjects Research Approval April 2018

Arm 1 study training April 2018

Patient enrollment starts May 2018

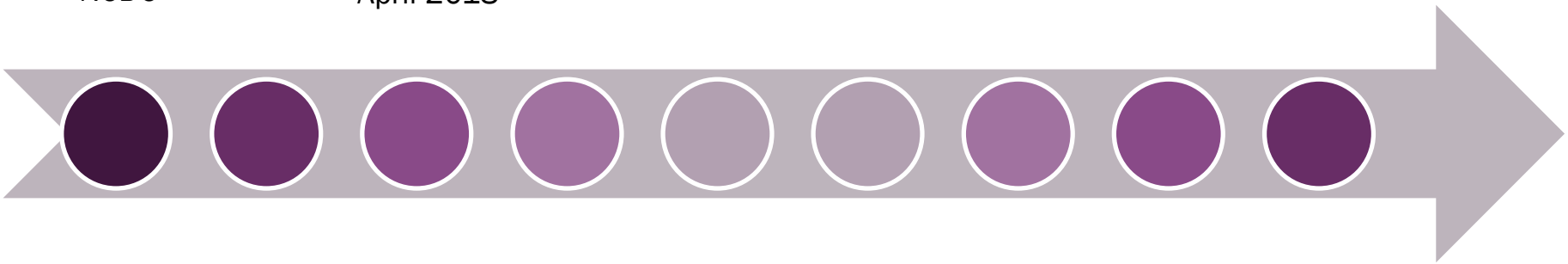
Reached 50% enrollment beginning of Nov 2018

Expected enrollment completed Arm 1 – Dec 2018

Arm2&3– Feb 2019

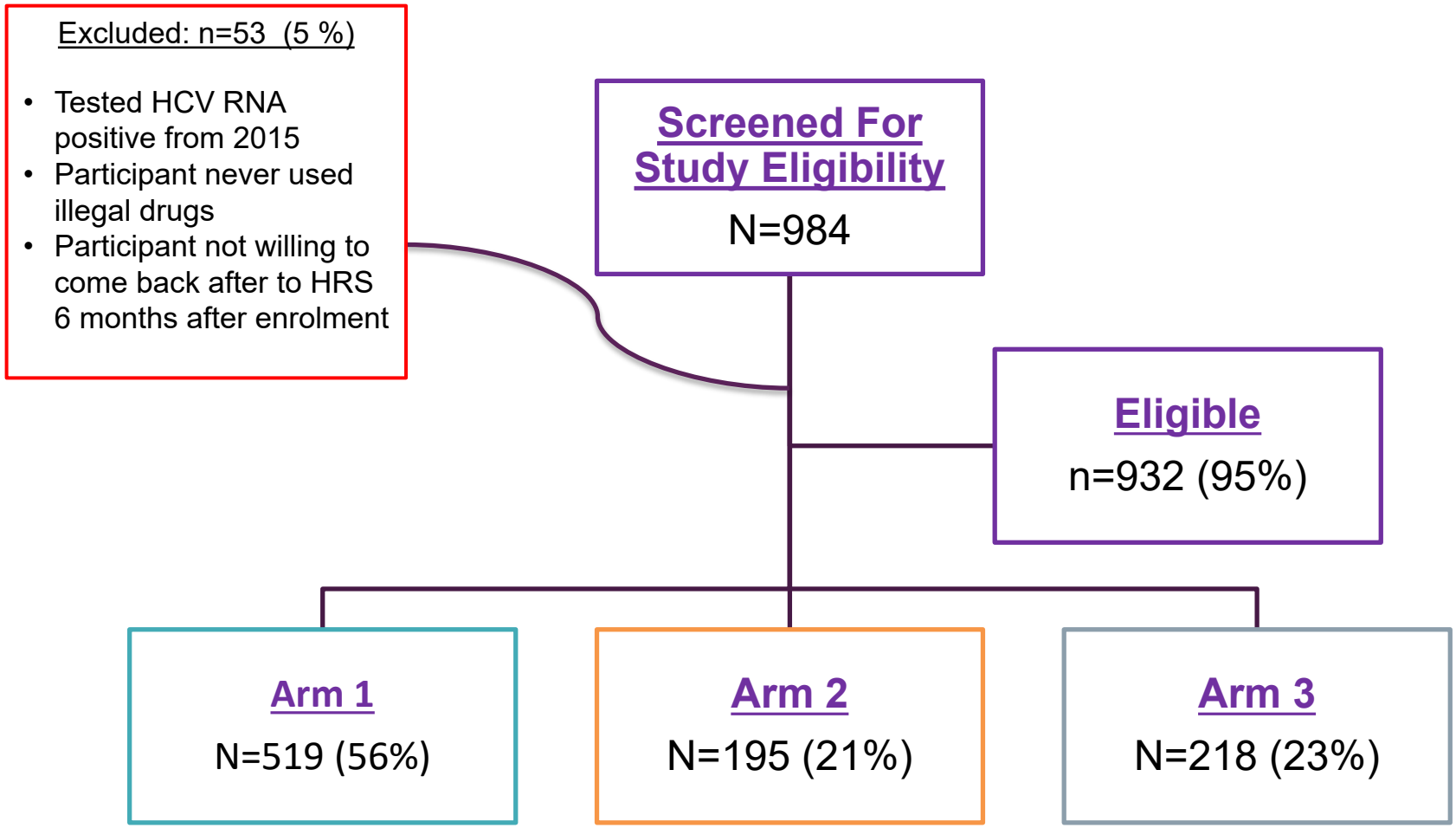
Expected 6 month chart review completed Aug 2019

Expected site close out Q3 2019



Preliminary Data:
May 2018 – November 2018

Screening and enrollment



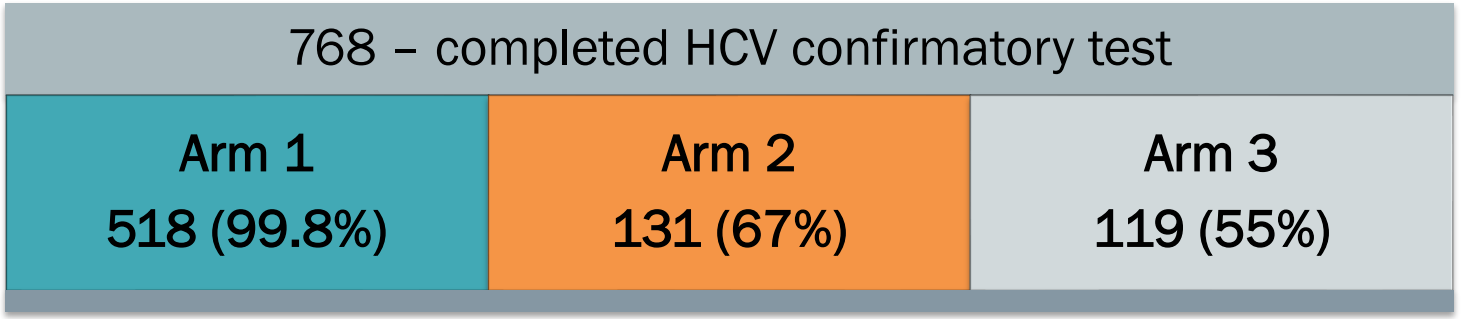
Patient Demographics and preliminary results

932 eligible and consenting participants enrolled to the study

- Gender: Male 890 (95.5%),
  Female 42 (4.5%)
- Age: Median 43 years,
  Range: 23 – 88
- Currently injecting drugs: 739 (79%)

Proportion of participants receiving HCV confirmatory test by arms

The proportion of study participants who have completed HCV viremia test as of November 1 2018, by arm



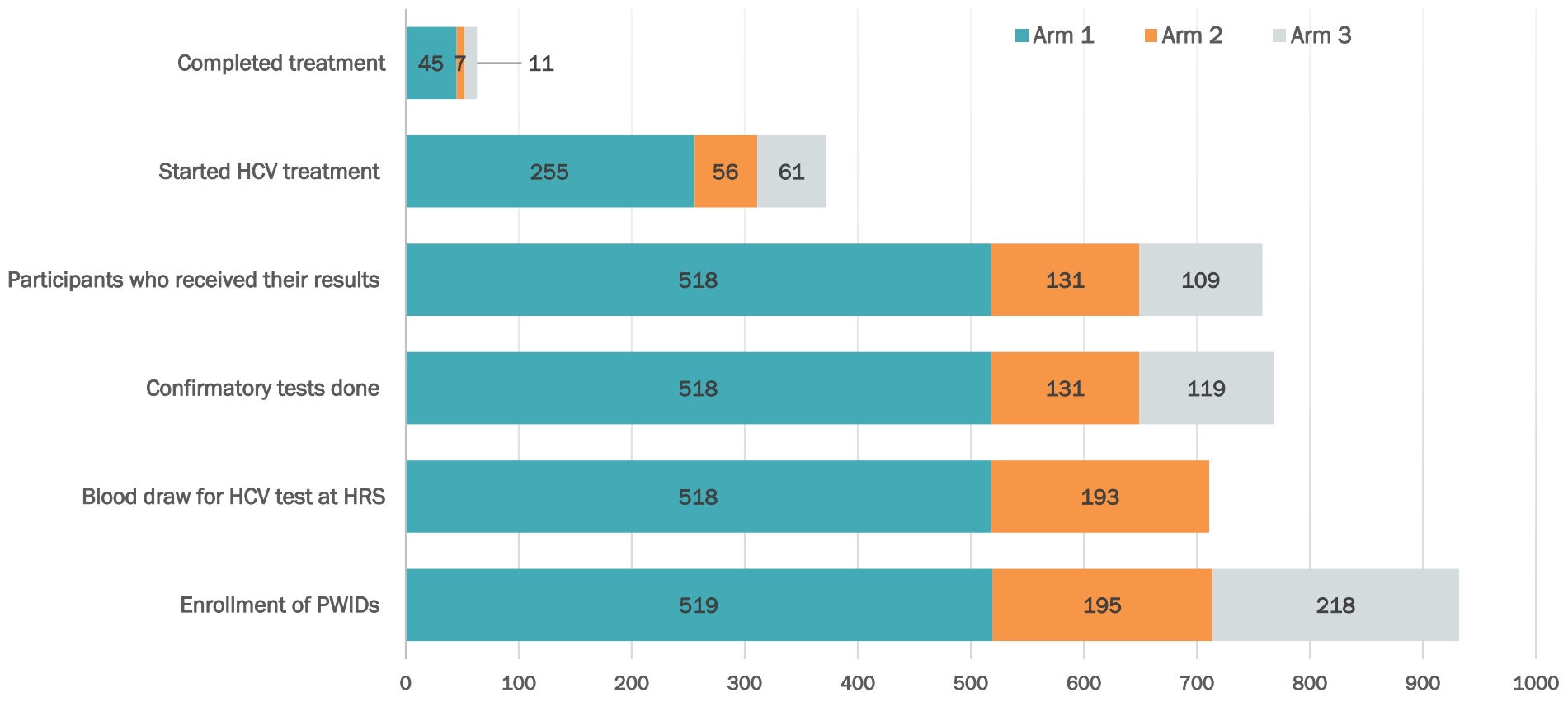
638 (83%) – Positive HCV Confirmatory results
130 (17%) – Negative results

Path to HCV Confirmatory Testing

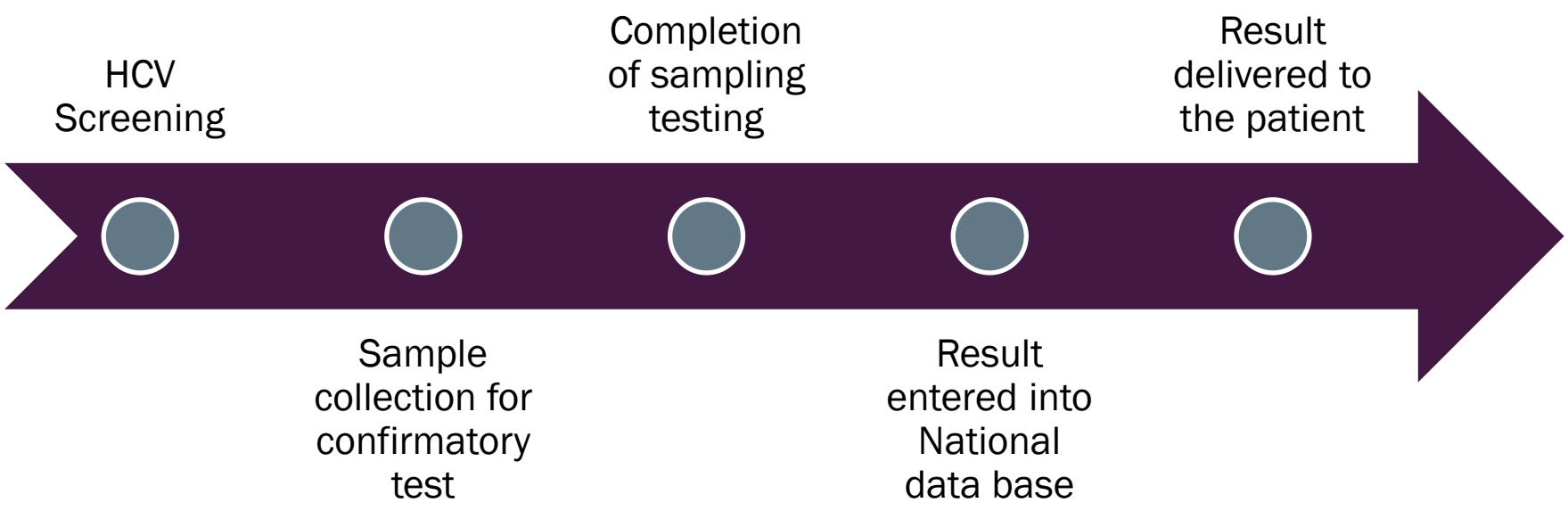
984 were evaluated for study eligibility

	Work Flow
932	Enrollment of PWIDs
710	Blood drawn for HCV confirmatory test at HRSs
768	Confirmatory tests done
758	Participants who received their results
372	Started HCV treatment
63	Completed treatment

Care cascade



Turn Around Time of results



Turn Around Time by arms

Time between / Arm	HCV screening and sample collection for confirmation test
Arm 1	Same day
Arm 2	Same day
Arm 3	2.2 days

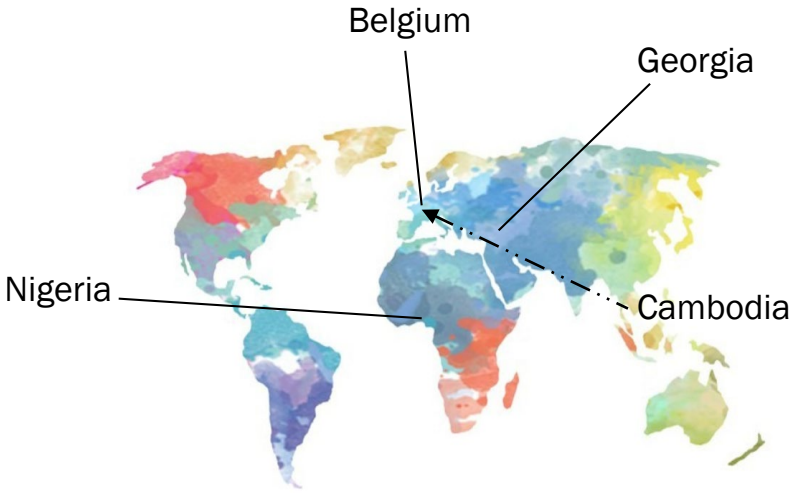
Preliminary Conclusions*

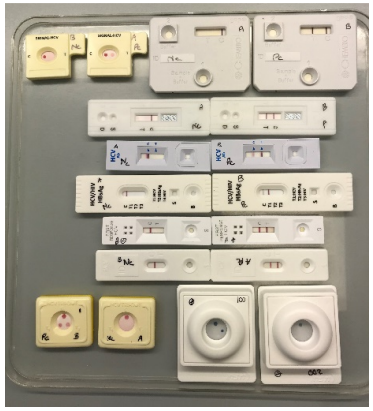
- Providing POC confirmatory viremia testing at HRS where PWIDs attend for care/needle provision improves access to HCV confirmatory viremia testing;
- On location based approaches to blood sample collection resulted in a larger proportion of participants receiving their confirmatory test results;
- The turnaround time was shortest where POC service was performed.

* Please note the feasibility/acceptability/costing data is not yet compiled and will be forthcoming

Other FIND projects in Georgia

HCV Rapid Diagnostic Test Study





International multicenter evaluation study

What

- Comparison of 10 Rapid Diagnostic Tests for the detection of HCV
- In total 1'800 archived EDTA plasma samples are analyzed on two lots of each test

Where

- Georgia: NCDC Lugar Centre;
- Nigeria: Nigerian Institute of Medical Research
- Belgium: Institute of Tropical Medicine -> samples from Cambodia

Why

- To assess diagnostic sensitivity and specificity in HCV-mono and HCV/HIV co-infected samples
- To assess operational characteristics of the tests (e.g. lot and reader variability)

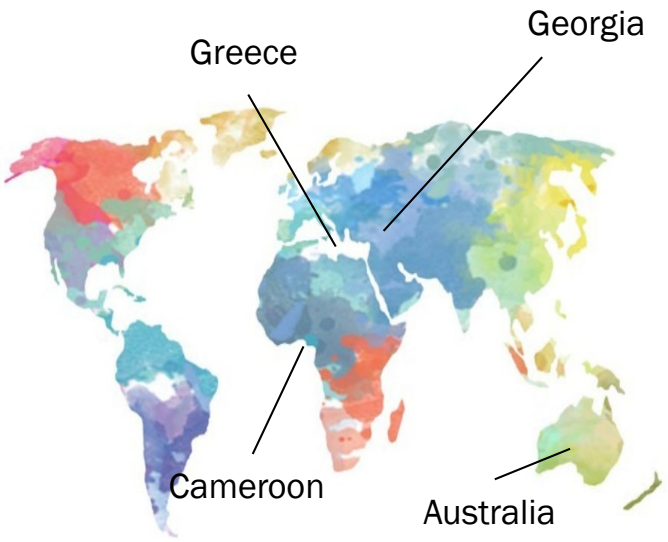
Study timeline

- October – December 2018

➢ *Georgia alone is running 7'600 RDTs in two months!*

HCV Dried Blood Spot (DBS) validation study

Prospective cross-sectional multicentre diagnostic accuracy study



What

- Validation of 3 DBS protocols for detection of HCV RNA in a high throughput platform
- In total 400 HCV RNA+ and 415 HCV RNA- will be recruited across all sites

Where

- Georgia: NCDC Lugar Centre
- Greece: Institute of Tropical Medicine
- Australia: NRL
- Cameroon: Centure Pasture Cameroon

Why

- To evaluate the performance of centralized HCV viral load (VL) assays from DBS
- A validated manufacturer protocol for DBS could faciliate greater use of sample transport for HCV testing

Study Timeline

- Second half of Jan 2019 – May 2019

HCV core antigen as test of cure study

What:
To estimate the diagnostic accuracy of HCVcAg assay in differentiating patients who have achieved sustained virological response (SVR) from those who fail SVR among those who have completed treatment for hepatitis

Study design:

A retrospective study on frozen samples of 131 relapsers which were HCV RNA positives at SVR12 between 2015 to 2016 in Neolab clinic. 62 SVR12 with HCV RNA non-detected

Where: Testing conducted at Lugar Center

Why:

- Potential to use of HCVcAg for test of cure or to assess re-infection for population at risk of infection

Study timeline:

- Last week of January 2019 - May 2019

HCV Genedrive study of use in intended settings

What:

Prospective diagnostic accuracy study

Lugar center and Hepa Plus

Study population:

- Individuals at high risk of HCV infection recruited at HRS Hepa Plus (Tbilisi)
- Sample size: 75 detectable HCV positive and 50 non-detectable HCV participants

Why:

- Study contribution to WHO PQ dossier and bring more molecular POC to market
- Would bring another molecular POC in Georgia for decentralised, low throughput HCV testing

Study timeline:

- December 2018 to March 2019

Thank you!

Special thanks to our partners in this endeavor!

We are grateful for the input and feedback of many of the organizations also doing great work in the area of HCV elimination in Georgia