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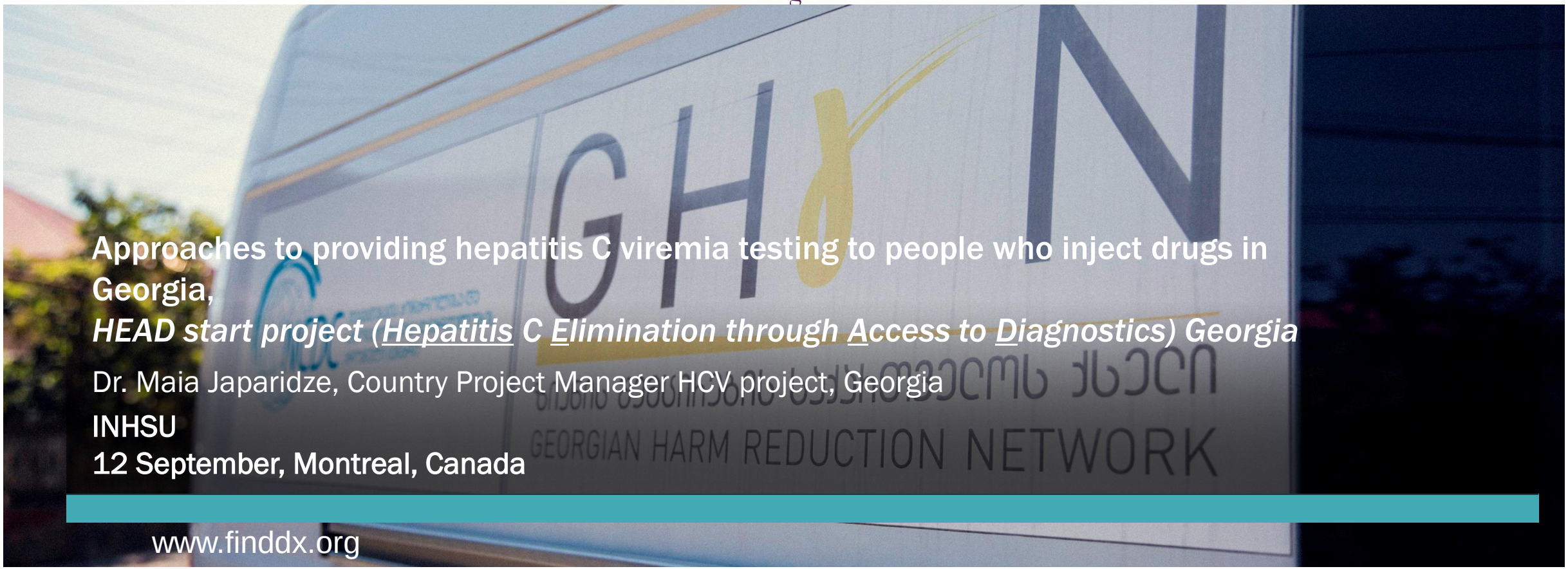

Approaches to providing hepatitis C viremia testing to people who inject drugs in Georgia,

HEAD start project (Hepatitis C Elimination through Access to Diagnostics) Georgia

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INHSU

12 September, Montreal, Canada

HEAD-Start Georgia

HEAD-Start study looking at impact of point-of-care HCV confirmation on care cascade among PWIDs

Objectives of the study:

- To determine whether the proportion of participants who receive results of HCV viremia testing differs between the Arms.
- To characterize the HCV care cascade for PWID identified through HRSs in Georgia, and quantify the proportion that go through each step in the cascade.

Partners:

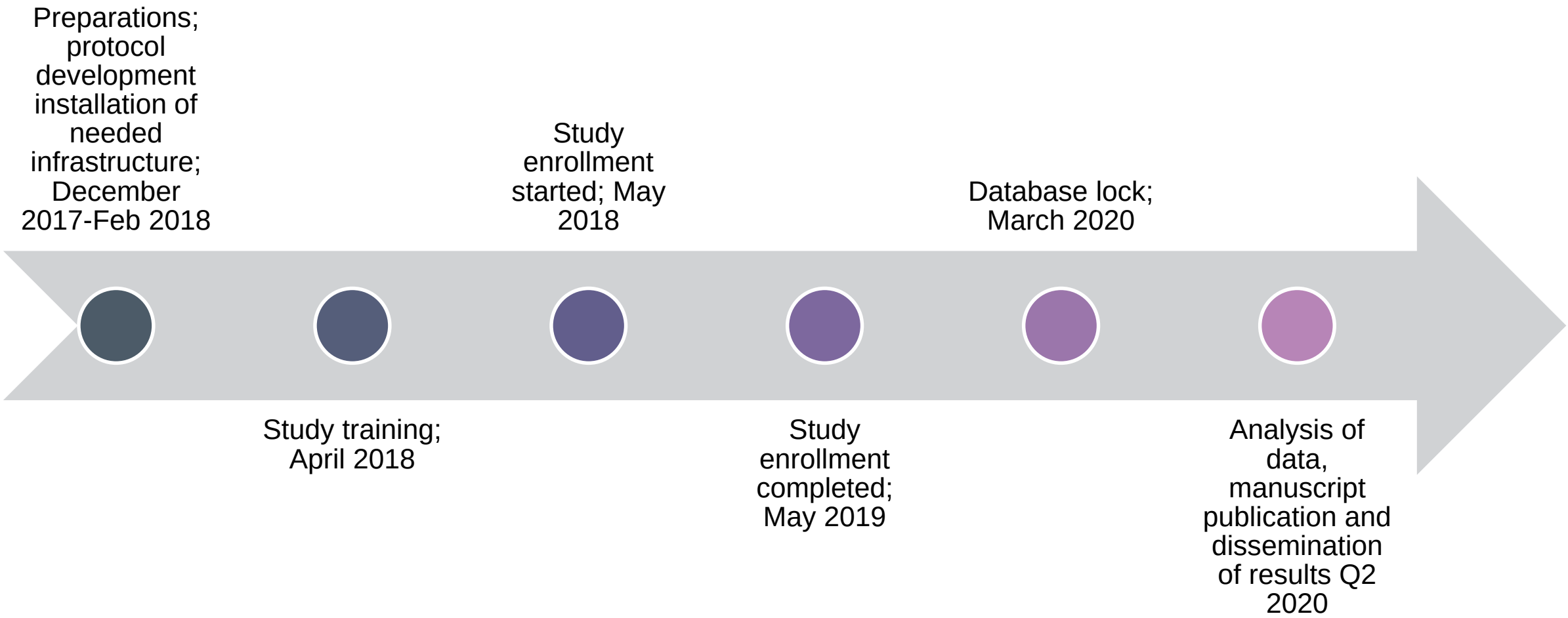
Georgia MoH, Georgia NCDC,
Georgian Harm Reduction Network,
Health research Union
Harm Reduction Sites

Epidemiology

Population: 3.7 million
HCV (Gen Pop) seroprevalence 7.7% [1]
HCV (Gen Pop) chronic infection 5.4% [1]
PWID: ~50,000 [2]
HCV prevalence among PWIDs ~66% [3]

1 *NCDC, National Survey, 2015*
2 *Addiction Research Development in Georgia Project, Drug situation in Georgia 2015, report*
3 *Bio-Behavioral Surveilllance Survey, 2014 - 2015*

Georgia HEAD-Start study timelines



HEAD-Start Georgia study design

Harm Reduction Sites

(8 HRS)

Non randomized assignment

Arm 1:

(on-site POC molecular)

4 HRS

- Blood draw at point-of-care service (HRS)
- HCV confirmatory testing
- HCV viremia results given at HRS on same day

1. Tbilisi New Vector
2. Zugdidi Xenon
3. Kutaisi New Way
4. Batumi Imedi

Arm 2:

(on-site blood draw for centralized cAg)

2 HRS

- Blood draw at point-of-care service
- Plasma shipped to central lab for HCV confirmatory testing

1. Tbilisi Akeso
2. Rustavi New Vector

Arm 3:

(patient who screens RDT+ referred to HCV treatment site SOC)

2 HRS

- Standard of care: patients referred to treatment center for blood draw and confirmatory testing

1. Gori Step to Future
2. Tbilisi New Way

Georgia HEAD-Start study sites

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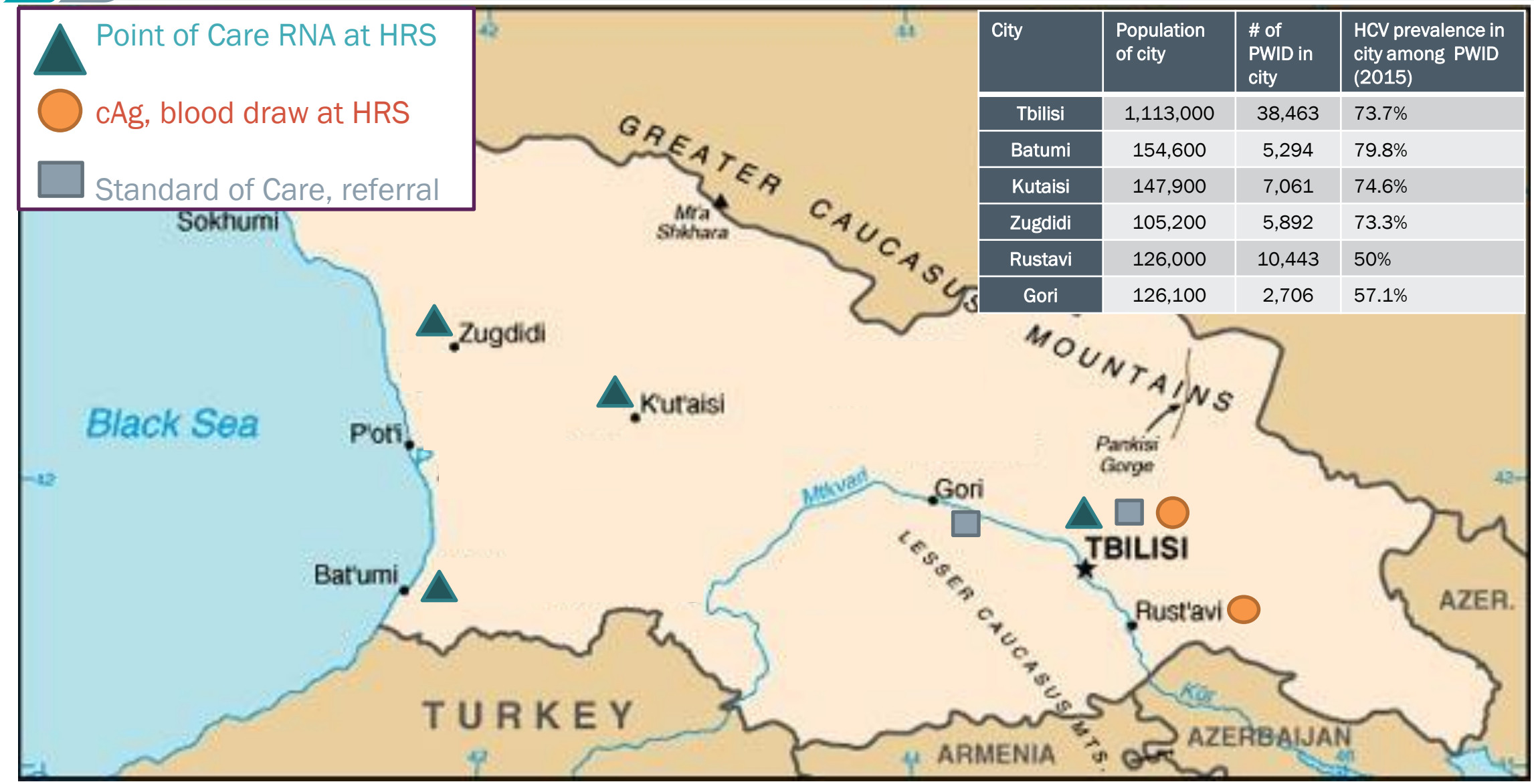


City	Population of city	# of PWID in city	HCV prevalence in city among PWID (2015)
Tbilisi	1,113,000	38,463	73.7%
Batumi	154,600	5,294	79.8%
Kutaisi	147,900	7,061	74.6%
Zugdidi	105,200	5,892	73.3%
Rustavi	126,000	10,443	50%
Gori	126,100	2,706	57.1%

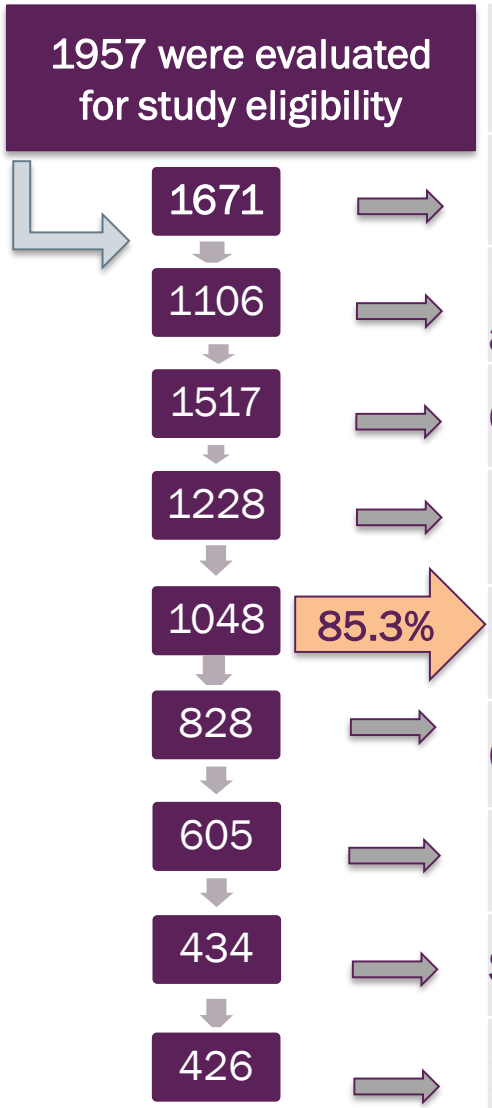
Proportion of participants receiving HCV confirmatory test by arms, preliminary data

The proportion of study participants who have completed HCV viremia test as of 1 Aug 2019 by arms

1517 – completed HCV confirmatory tests		
Arm 1 620 (100%)	Arm 2 485 (99.8%)	Arm 3 412 (72.9%)

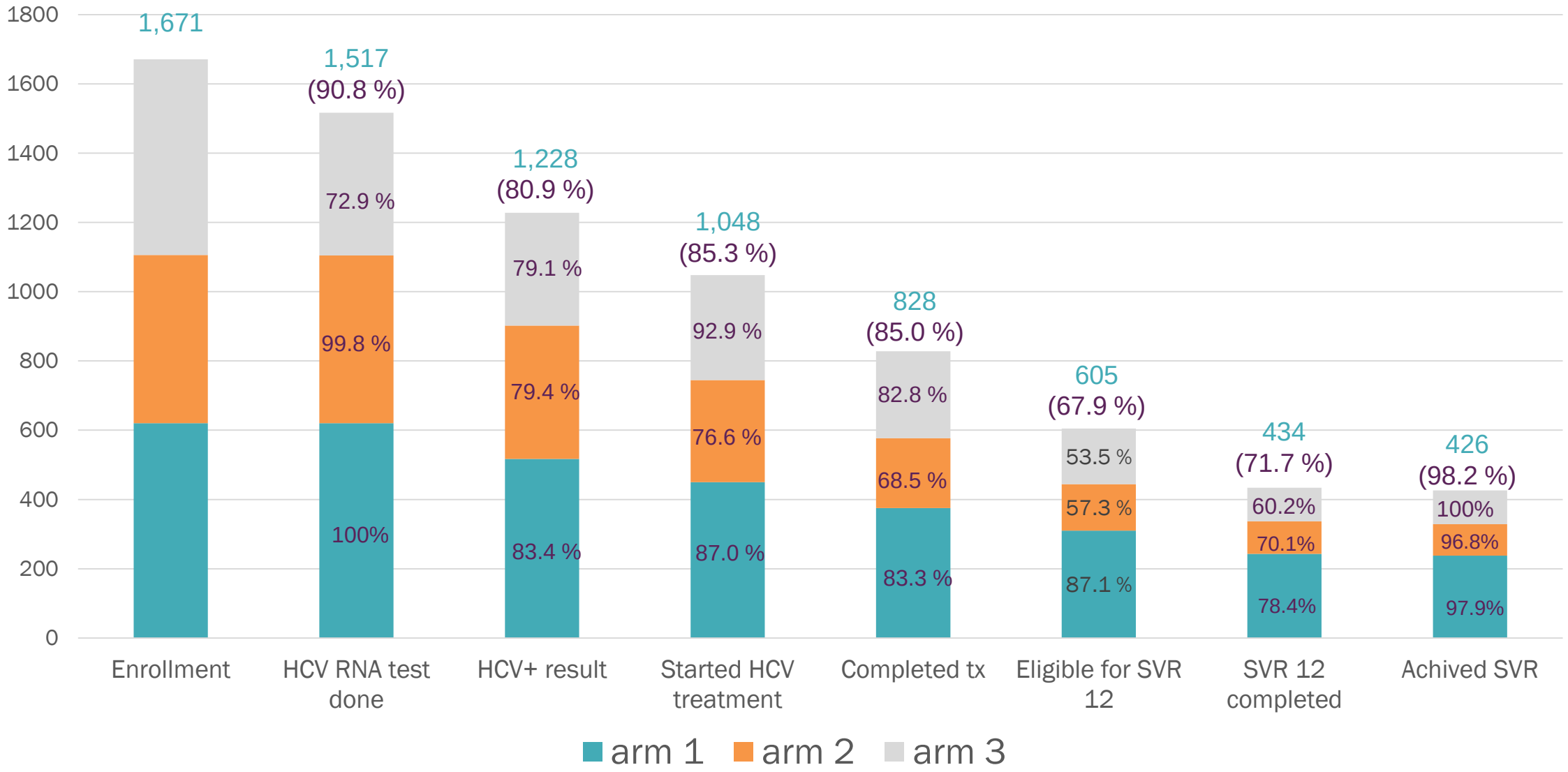
1,228 (80.9%)	–Positive HCV Confirmatory results
278 (19.1%)	–Negative HCV Confirmatory results

HEAD-Start Georgia; preliminary data: May 2018 – 1 Aug 2019



Cascade of care	Arm 1	Arm 2	Arm 3
Enrollment of PWIDs	620	486	565
Blood drawn for HCV confirmatory test at HRSs	620	486	N/A
Confirmatory tests done	620	485	412
HCV Conf Positive results	517 / 83.4%	385/ 79.4%	326 / 79.1%
Initiated HCV treatment	450	295	303
Completed treatment	375	202	251
Eligible for SVR 12	310	134	161
SVR 12 completed	243	94	97
Reached SVR 12	238	91	97

HEAD-Start Georgia study care cascade; preliminary data: May 2018 to 1st August 2019



Early treatment cessation

Arm	Started treatment (n)	Stopped treatment (n)	%
Arm 1	450	16	3.8
Arm 2	295	7	2.4
Arm 3	303	8	2.5
TOTAL	1048	31	3.0

Cities	Arm	Started treatment (n)	Stopped treatment (n)	%
Tbilisi	1, 2, 3	355	8	2.3
Zugdidi	1	89	10	11.2
Kutaisi	1	231	0	0.0
Batumi	1	89	3	3.4
Rustavi	2	148	5	3.4
Gori	3	136	5	3.7
	Total	1048	31	3.0

Turn around time by arms, preliminary data _ 1 Aug 2019

Time between (mean) / Arm		HCV screening and sample collection for confirmation test	Sample collection and completion of sample testing	Completion of sample testing and result entered into National Database	Result entered into database and result delivered back to patient	Total Time
Arm 1	n=620	Same day	2 hr 24 min	19 hr 12 min	25 minutes*	2 hr 49 min / 22 hr 01 min
Arm 2	n=485	1.3 day	5.5 days	4.1 days	10.6 days**	21.5 days
Arm 3	n=412	3.6 days	6.0 days	2.6 days	6.4 days	18.6 days

* time between completion of sample testing and result delivered back to patient

** It is included the time that are spent for repeated test of PCR in case of cAg test result is negative or it is in grey zone.

Demographic data; preliminary

	Total		
Age (range, average)	Range 19-88	Average 44	n=1671
Gender	Male 95.4%, n=1594	Female 4.6%, n= 77	
Currently injecting drugs	Yes 79.1%, n=1289	No 24.9%, n=382	
Age started injecting drugs	Range 13-48 yr	Average 21 yr	
Highest grade completed	Primary 0.6% n=10	Secondary 59.2% n=989	Post secondary college 40.2%, n=672
Current employment status	Employed: 20.0%, n=335 Self-employed: 14.7%, n=245 Un-employed: 64%, n=1061 Temp-employed: 0.7%, n=11 Retired: 1%, n=17 Student: 0.3%, n=2		

Preliminary Data _ Co-infections

	Total
Ever started treatment for HCV (before national program began; 2015)	n=10
Self reported ever tested for HIV	Yes 95% No 5%
Self reported HIV status	HIV+ n=14
Self reported currently on ART	of those 3 reported ever being on ART and 2 currently on ART
Self reported TB	8 reported as having active TB (in the past), currently none are on treatment

Preliminary Data _ Behavior factors

	Total
Attending harm reduction programme?	50% yes 50% no
If yes, what prorgramm (NSP, OST, Peer ed, Case management)	587 engaged in single HRS services, the most popular being NSP (n=404) followed by OST (n=138) Of the 56 that engage in multiple services NSP and OST was the most common (n=42)
Type of drug	The most commonly reported drug used was opioids (n=1272), followed by marijuana (n=1075), amphetamine (n=426), cocaine (c=365), club drugs (n=189)
Method of use	Of the 1272 who reported using opioids, 1232 reported the main method of use injecting. Of the 426 who reported using amphetamine 416 reported the main method of use injecting

Preliminary Data _ Risk factors

	Total
- Of all the times you have injected in the past 6 months, how often were you injecting with other people?	15% report never, 20% less than half, 10% more than half, 21% always, 34% cannot recall
- Of all of the times you injected with other people in the last 6 months, how often did you inject with syringes that had been used before by someone else, even if the syringe was cleaned first?	74% reported never sharing needles, 25% reported sharing needles at least sometimes 1% declined to answer

Preliminary conclusions*

- 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

HEAD-Start
Hepatitis C Elimination through Access to Diagnostics

Special thanks to our partners and study participants!

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

Thank you !