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Introduction of Sofosbuvir based HCV treatment in Ukraine

Sergey Filippovych

Director: Treatment, Procurement and Supply Management

EUROPEAN HIV HEPATITIS CO-INFECTION (EHHC)

CONFERENCE

Dr Sergii Filippovych

Alliance, Kiev, Ukraine

COMPETING INTEREST OF FINANCIAL VALUE ≥ £1,000:	
Speaker Name	**Statement**
Sergii Filippovych	As a part of expanding access to treatment of hepatitis C from April 2015, the ICF «International HIV/AIDS Alliance in Ukraine» is implementing the project « Scaling up accessible and effective HCV treatment through community-based treatment model for most vulnerable populations in the resource constrained Ukraine». Alliance Ukraine has received a grant from Gilead Sciences Inc. to finance the implementation of the project. It should be noted that Sergii Filippovych has no personal interest in the grant of Gilead. Salary for his work in Alliance Ukraine is not paid from the budget of the Gilead project.
Date	1/12/2015

Situation in Ukraine

- Population: 43 million
- 218,000 HIV-positive people or 0.58% of estimated adult prevalence (2015, Bul. #44)
- **HCV/HIV co-infection** is registered in **38,4%** among all new registered HIV cases (2014, Bul. #43)
- **124,279 PLWH** currently under medical supervision in AIDS clinics (2015, does not include AR Crimea)
- The epidemic is driven primarily by *injecting drug use*, although heterosexual transmission also plays an important role.
- Estimated # of PWID in Ukraine is 310,000, Main injectable drug of abuse – home-made acetylated poppy straw extract (opioid)
- PWID receiving **OST** - 8 385 (**55% HCV** positive, n=4 606)
- **HCV** prevalence among **PWID** is **55%** (AU, BBS 2013)
- **HCV** prevalence among **CSW** is **13%** (2014, Bul. #43)

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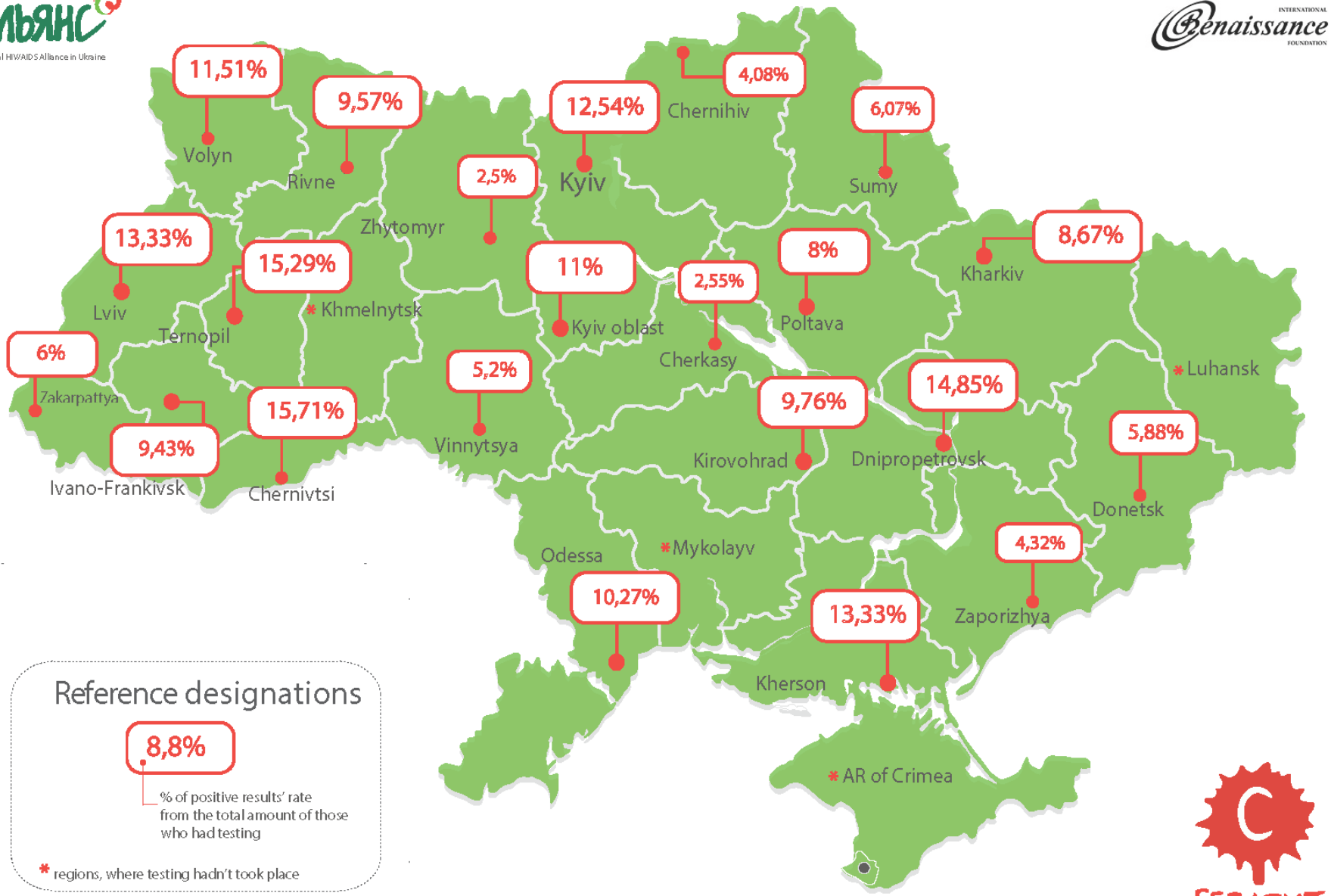
The results of the express Hepatitis C testing in the Ukrainian towns within the framework of all-Ukrainian «We demand Treatment!» campaign

July 2014

Альянс
International HIV/AIDS Alliance in Ukraine

International Renaissance Foundation



Reference designations

8,8%

% of positive results' rate from the total amount of those who had testing

* regions, where testing hadn't took place

ГЕПАТИТ С

HCV treatment for OST patients

October 2013 – introduction of HCV treatment with pegylated interferons for HIV positive OST patients

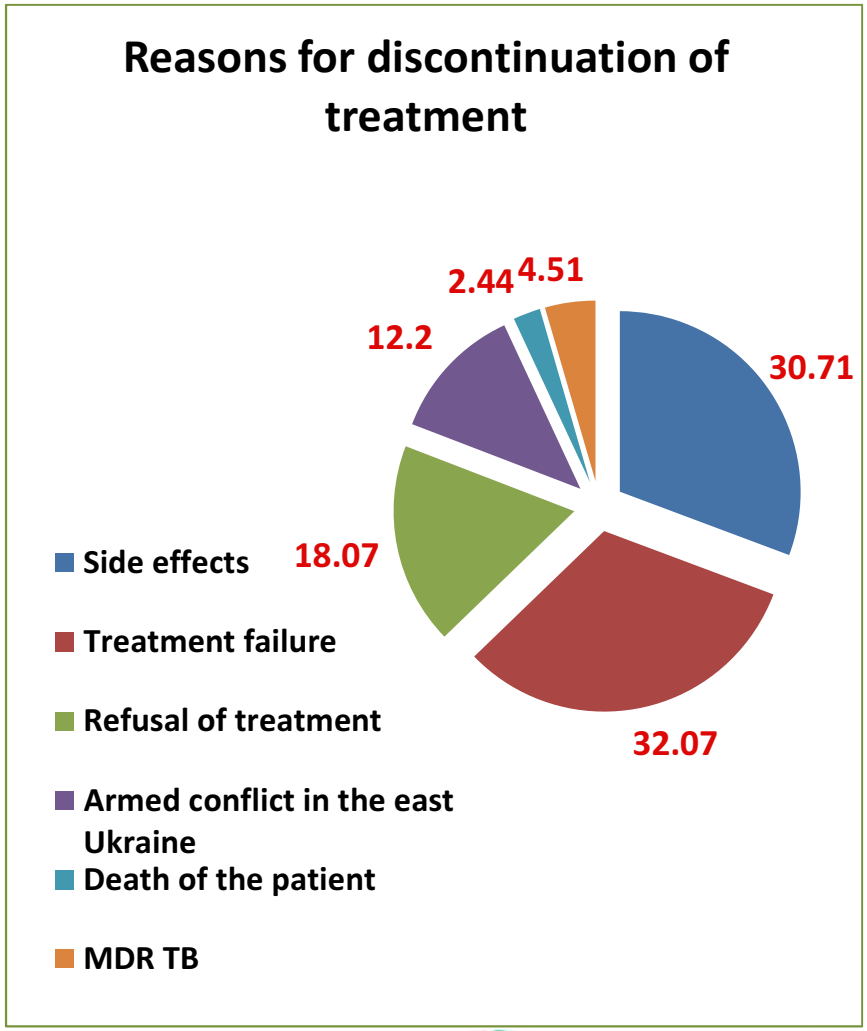
December 2014

- **135** patients out of them:
- **119** – ART+OST (57% methadone, -
- 43% buprenorphine)

Genotyping: 1st - **56%**
2nd - **6%**
3rd - **38%**

33% - undetected HCV RNA at week 24 with 1, 2 and 3 genotypes

42% of patients drop out of the treatment



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Scaling up accessible and effective HCV treatment through community-based treatment model for most vulnerable populations in the resource constrained Ukraine

Overall goal: to ensure access to HCV treatment for Most at Risk Populations and develop innovative community based service delivery models to include medical and social support of treatment with Directly Active Antiviral (DAA) regimen.

Main activities:

- Organization of medical and social support for patients receiving Sofosbuvir based HCV treatment
- Trainings for medical and social staff
- Laboratory diagnostics for treatment monitoring and follow-up
- Operational research to identify the most effective model
- Integration of Sofosbuvir into National HCV treatment protocol

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Launching Sofosbuvir based HCV treatment

Project start: April 2015

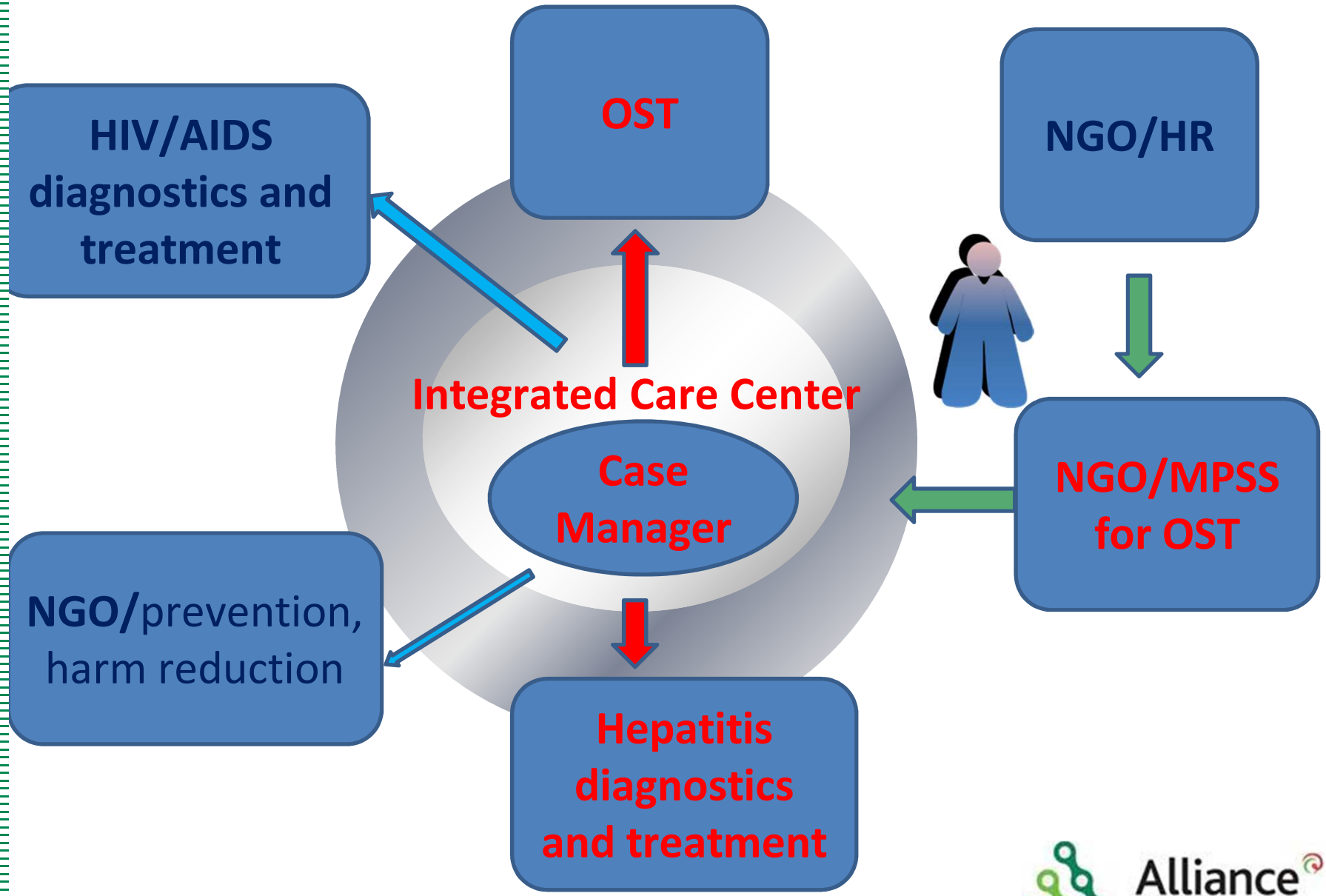
Implementation plan:

- Phase 1 – **250**, 8 healthcare facilities
- Phase 2 – **500**, 17 healthcare facilities
- Phase 3 – **750**, to be selected

Phase 1 results:

- Training for medical and social staff
- Laboratory monitoring of the HCV treatment (HCV RNA Quantitative) with provision of the 50% testing discount
- Cooperation with MoH on Peginterferon allocation for the Project from the National HCV Program
- Social support to the patients during the treatment
- Inclusion of the Sofosbuvir in the national clinical protocol

Integrated care model



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Cohort characteristics:

Inclusion criteria phase 1:

- HIV/HCV Confection (250)
- ≤F2, F3-F4 METAVIR
- PWID, OST, other MARPs, receiving ART

Treatment regimens:

Group of patients	Treatment regimen	Treatment duration
Genotype 1 and 4	sofosbuvir + ribavirin + Peg-IFN-alpha	12 weeks
Genotype 2	sofosbuvir + ribavirin	12 weeks
Genotype 3*	sofosbuvir + ribavirin + Peg-IFN-alpha	12 weeks

* In exceptional cases, for HCV genotype 3: without cirrhosis and / or with absolute contraindication to PEG-IFN-alpha, possible regimen is sofosbuvir + ribavirin for 24 weeks.

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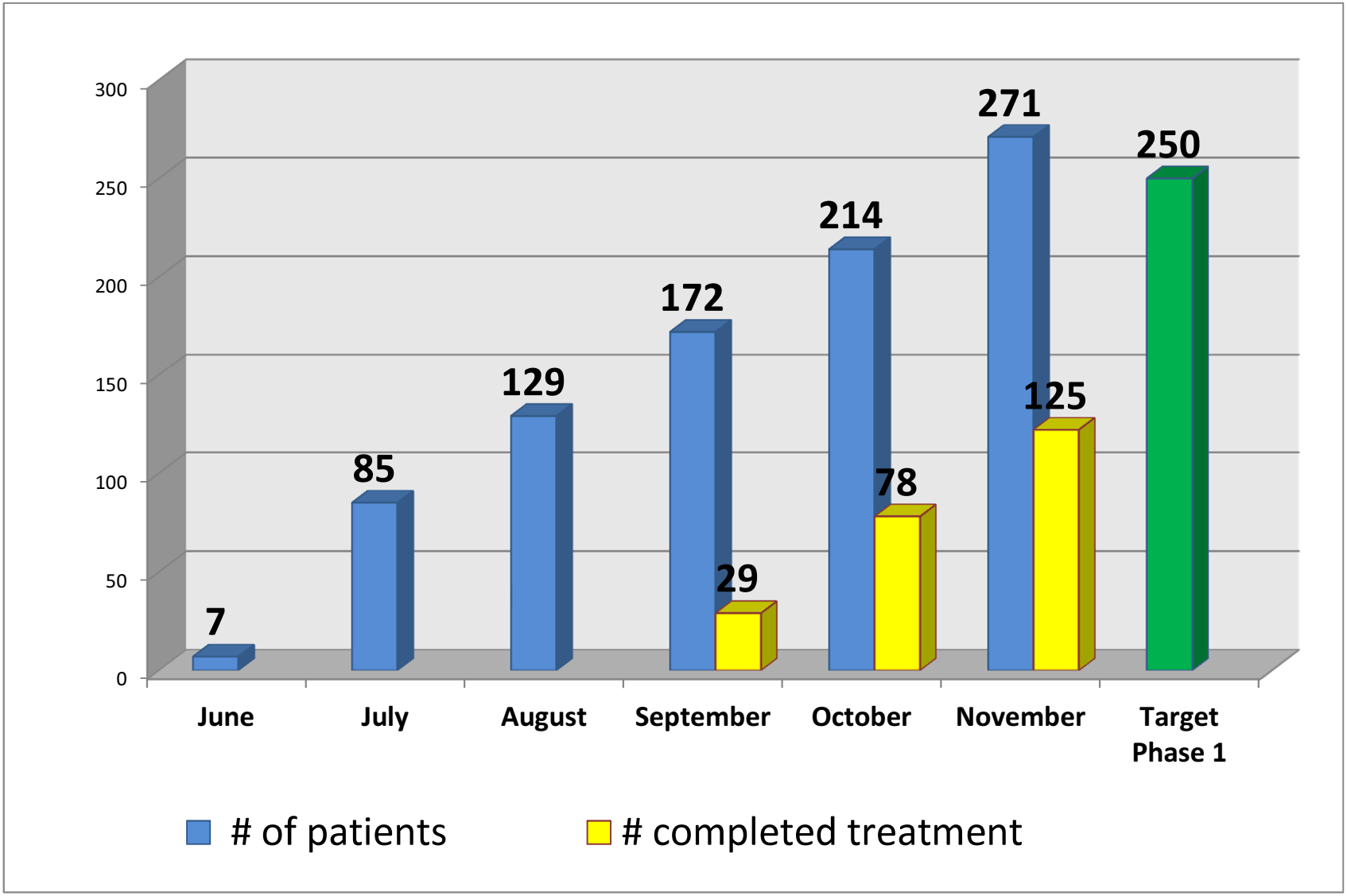
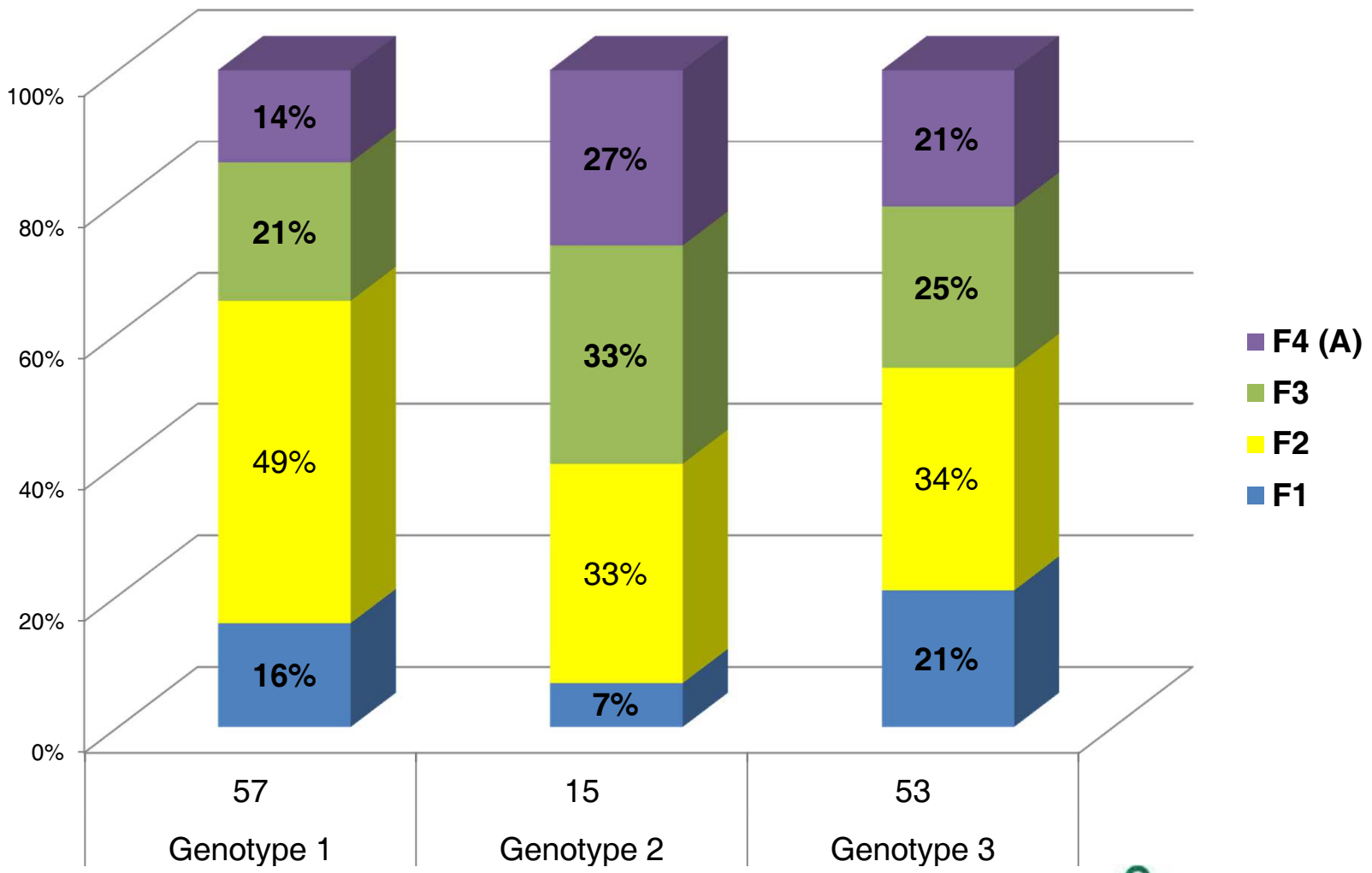
Enrollment rates, Phase I



Patients' characteristics (1)



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Patients' characteristics (2)

98% patients have HIV/HCV co-infection

91% out of HIV/HCV are receiving ARV treatment

6 OST patients

Results:

Overall **125** – have completed HCV treatment

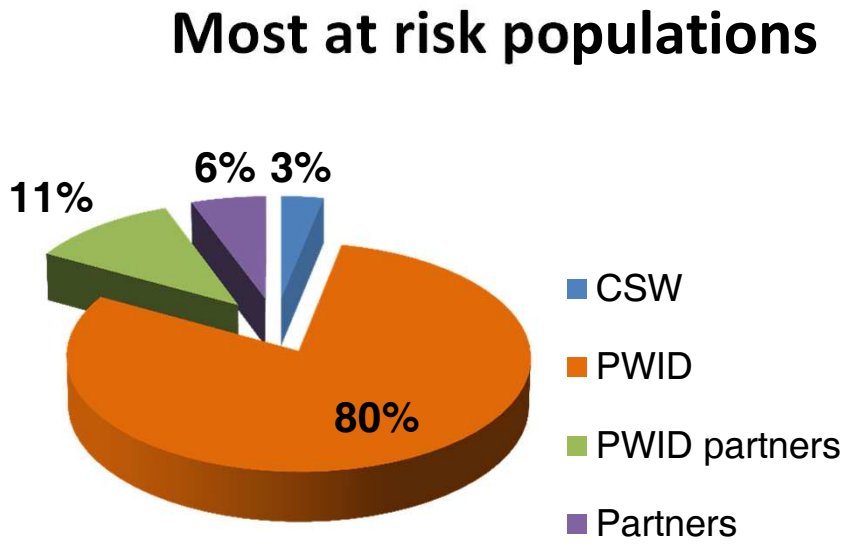
112 patients have received HCV RNA test result

111 have undetected HCV RNA result End of Treatment (EOT)

SVR 12 W:

1 patient – G1, F 4 (A), experienced (SOF+PEG+RBV, 12 W)

1 patient – G3, F 4 (A), naïve (SOF+PEG+RBV, 12 W)



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Conclusions:

Challenges:

- Financial burden of the pretreatment diagnostics for MARPs patients
- Strong beliefs among patients related to the HCV treatment such as “not effective”, “accompanied by lots of side effects”

Lessons learned:

- Sofosbuvir based HCV treatment in PWID cohort has shown high retention rate and treatment adherence
- 99% of all patients who have completed 12w HCV treatment course have undetected HCV RNA at the End of the Treatment

Next steps:

- Launching Phase 2: scale up for 17 healthcare facilities, 689 treatment courses
- Operational research on the Sofosbuvir based treatment program
- Continue building capacity of the healthcare institutions by establishing cooperation with community based NGOs, provision of trainings for medical staff

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Thank you!

- Dr. Sanjay Bhagani
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- T. Barnard
- O. Burgay

filippovych@aidsalliance.org.ua

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