Background. While Germany has a long tradition in HIV research with many well-established regional cohorts, there was a lack of collaborative efforts toward harmonized data collection and biobanking, both key strategies for efficient translational research projects. Key challenges are heterogeneity of data systems and privacy concepts, of existing study and data collection protocols, and sample collection, storage, and sharing.

Methods. In 2013, we established the Translational Platform HIV (TP-HIV) with support of the German Centre for Infection Research (DZIF) as a collaboration between university hospitals and specialized HIV care centers throughout Germany. After assessing the individual needs of all partner sites, we have taken comprehensive action to create a common platform for collaboration in all research stages. We developed protocols, rules of operation, biobanking strategies, and privacy concepts for all collaborating partner sites. Patients infected with HIV (PLWH) who sign the informed consent for the TP-HIV are pro- and retrospectively included in the cohort.

Results. To date, the TP-HIV infrastructure is implemented at 27 member sites from 11 cities, potentially extending to more than 20,000 patients currently treated for HIV across Germany. Facing the special needs in the German research environment, the TP-HIV established a unique data- and biomaterial collection allowing expedited translational research and reduce project overheads, regulatory burden, and data security regulations for investigators. By active surveillance, rapid access to individual patient groups such as patients with acute HIV infection, TP-HIV is an ideal platform for early phase clinical trials with new drug candidates. Researchers with clinical, biological, epidemiological, and statistical expertise have been brought together within the TP-HIV, which enables an effective translational chain from bench to bedside and back. New collaborations have been established with currently 23 active study protocols.

Conclusion. The TP-HIV has demonstrated to be a powerful tool for generating and testing research hypotheses in PLWH. In the future, we will work to further expand our network and address the pressing needs in the German research environment. 

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Background. The Antibody-mediated Prevention (AMP) trials (HVTN 704/HPTN 085 and HVTN 703/HPTN 081) are the first efficacy trials to evaluate whether VRC01, a broadly neutralizing antibody (bnAb) that targets CD4 binding site of HIV envelope, prevents HIV acquisition in uninfected individuals. In these ongoing tria ls, 10 intravenous (IV) infusions of VRC01 are given every 8 weeks over a period of 2 years. We report on interim operational feasibility, enrollment and safety.

Methods. Participant recruitment was enhanced by extensive community engagement and education. Eligible participants were randomly assigned 1:1:1 to 10mg/kg, 30mg/kg of VRC01 or saline placebo. HVTN 704/HPTN 085 enrolled individuals ≥ 18-59yrs of age with prior HIV seronegative testing and no history of HIV or any other human immunodeficiency virus (HIV). HVTN 703/HPTN 081 enrolled high-risk heterosexual women at 20 sites in Botswana, Kenya, Malawi, Mozambique, South Africa, Tanzania, and Zimbabwe. HIV testing occurs monthly.

Results. In October 2018, the AMP trials completed enrollment of 4,625 participants. Enrollment met or exceeded targets throughout the trial period, peaked at 298 participants/month, and was slowed mid-trial to allow for sufficient supply drug at trial sites. In HVTN 704/HPTN 085, 2701 (target N = 2700) MSM/TG participants 18-59yrs were enrolled with median age of 28, 99% born male; 90% identified as male gender; and 5% TG female. Race/ethnicity was 32% White, 15% Black and 57% Hispanic/Latino/a. 28% had a sexually transmitted infection (STI) including gonorrhea (GC), chlamydia (CT) or syphilis at enrollment. In HVTN 703/HPTN 081, 1924 participants were screened for enrollment (target N = 1900) women 18-44yrs were enrolled with median age of 26;100% were female; 53% female gender, 47% gender not assessed; 99% were Black, 26% had a STI at enrollment including GC, CT, trichomonas or syphilis. Overall 36,945 infusions have been given so far with no serious procedural complications due to IV administration. Retention and adherence to the rigorous study schedule (monthly visits for 2 years) remained within an acceptable range.

Conclusion. The AMP trials have exceeded enrollment of target populations and are maintaining high rates of retention. With exceptional safety and operational feasibility, they are paving the way for future large-scale bnAb trials for HIV prevention and/or treatment.

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1274. The PrEP Care Continuum Among an Uninsured Patient Population
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Background. Despite the clear preventive benefits of HIV Pre-Exposure Prophylaxis (PrEP), uptake among populations at highest risk of HIV acquisition has been limited by lack of health insurance and access to care. In March 2018 we opened a free PrEP clinic for those without insurance. We provide HIV prevention services, following the CDC guidelines, with PrEP case manager navigation, medical management, and medication for at-risk individuals free of charge.

Methods. Half-day clinics were organized on a twice-monthly basis with supervision provided by two infectious disease specialists and several other licensed providers/fellows, with supporting case managers and medical assistants. Medical students were enlisted to help organize and manage patient visits. All patient visits were preceded by discussion with case managers to document insurance status, followed by a sexual history and general physical examination by medical students and supervisory licensed providers. We performed all laboratory testing, diagnostics, and follow-up visits per CDC guidelines.

Results. From March 2018 to 2019, 193 self-identified at-risk patients scheduled an appointment; 157 unique patients were seen and all deemed eligible for PrEP per CDC guidelines. Of those eligible for PrEP, 140 (89%) received a prescription and started emtricitabine/tenofovir and 115 (73%) remain in care with ≥2 visits completed. Of the 25 no longer in care at our clinic, 6 have insurance or Medicaid (2 continue to be seen in our insured PrEP Clinic), 1 reports no HIV risk factors, and 1 is over-income for pharmacy patient assistance. Patients enrolled in clinic are largely male (145, 92%); 74% ≤ 34, a disproportionate fraction belonging to a minority racial/ethnic group (67, 43%), with a majority Latinx (60, 38%). A total of 48 STI cases were identified, mostly rectal chlamydia, rectal and pharyngeal gonorrhea (38%, 19%) and 9 (19%) cases of syphilis, and no new HIV or HCV infections. At the first visit, 17% of our patients have an STI and at subsequent visits 22% have a new STI.

Conclusion. Implementation of a free PrEP clinic for uninsured patients is a feasible and effective strategy to reach key populations at risk for HIV. STI rates are high in our population and increased after starting PrEP.