https://doi.org/10.1038/s44355-025-00028-w

# Closing the gap in HCV care: strategic collaboration between industry, academic, community, and nonprofit researchers

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Increased funding for hepatitis C virus (HCV) research and care delivery is needed to support effective programs for vulnerable communities and meet the WHO 2030 targets for HCV elimination. Strategic collaborations among industry and non-industry stakeholders can address this need. Establishing clear expectations, transparency, and investigator independence in these partnerships can enhance and accelerate HCV elimination efforts. Similar collaborative partnerships can be extended to address challenges in other therapeutic areas.

Despite intensive efforts to eliminate the hepatitis C virus (HCV), approximately 50 million people worldwide have an active infection, and about 1 million new cases emerge annually[1,2]. In 2016, the World Health Organization (WHO) identified HCV as a major public health threat and set a target to eliminate it by 2030. However, insufficient funding for HCV research and health care delivery remains a barrier to achieving HCV elimination[1]. Collaboration between industry, academic institutes, communities, and nonprofit organizations offers a promising solution[3]. Industry companies can provide vital strategic and financial support, including research resources, equipment, patient care through screening and treatment access, conference attendance funding, collaborative opportunities, and publishing strategies[4]. Nonetheless, such partnerships face challenges, in part due to the negative perception of industry involvement in academic and/or community health research. To overcome this barrier, transparency between industry, academic institutes, communities, and nonprofit organizations is essential, ensuring independence in research design and interpretation while maintaining flexibility to adapt research based on patient recruitment and data outcomes.

## The value of industry, academic, community, and nonprofit partnerships for HCV elimination

Several factors determine the success of industry, academic, community, and nonprofit partnerships that contribute toward HCV elimination (Fig. 1). While expectations may differ, it is essential that they are clearly defined early in the collaboration. Expectations may include scheduling regular project status calls between the partners to promptly identify and address any issues, and identifying areas where the academic and nonprofit investigators might need additional support. Early planning also helps establish the roles and responsibilities of each stakeholder, which minimizes the risk of conflicts of interest that could impact the interpretation of study findings. Transparent communication between the partners should occur throughout the collaboration for the timely exchange of opinions and feedback. Also, academic, community, and nonprofit investigators should retain full independence in directing the research (e.g., identifying where infection surveillance is needed across different geographic regions), analyzing the data, and publishing the findings and interpretations. These steps help to safeguard study integrity, which fosters intellectual trust among the wider research community.

When these steps are embraced, partnerships with pharmaceutical companies can play a crucial role in advancing HCV elimination efforts by supporting research that might otherwise lack sufficient funding, impact, or reach. Funding can take multiple years (e.g., up to 20 months for the US National Institute of Allergy and Infectious Diseases) to reach approval prior to project initiation; however, funding from industry can be granted on shorter timelines, which is needed to rapidly implement care and publish study results. Reducing time to project initiation is vital for translating drug efficacy to effectiveness in HCV elimination, which is in the best interest of pharmaceutical companies, governments, and academic and nonprofit investigators. Pharmaceutical companies can also provide valuable insights into emerging trends in screening, treatment, reimbursement, and support for specific patient populations. For example, the Polaris Observatory, which receives industry funding, was established to promote global adoption of hepatitis elimination programs by providing reliable country-level data to help inform policy decisions[5]. In some regions, such data and intervention programs would otherwise be unavailable. Enabling informed decision-making by public agencies and national governments that may lack the resources or capacity to independently support such initiatives is crucial for achieving HCV elimination. These initiatives are even better suited to local efforts, where screenings can be tailored to specific needs, rather than at the national level, which tends to rely on broader criteria. By supporting these local efforts, pharmaceutical companies can help improve linkage to care and aid the development of treatment guidelines for specific patient populations. Moreover, the insights gained from HCV micro-elimination initiatives must be shared with the wider health professional community to ensure long-term impact[6]. Pharmaceutical companies can support this goal by fostering connections among health professionals through conferences and workshops.

## The unique design of the LEGA-C program on HCV elimination

In 2016, the Local Elimination Programs Leading to Global Action in HCV (LEGA-C) program was launched to support efforts of health care

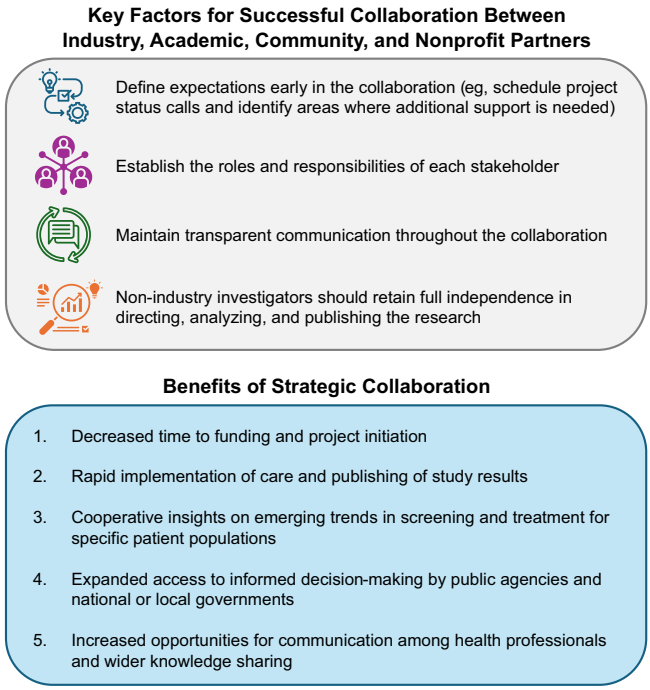


**Fig. 1** | Key factors for a successful partnership between industry and non-industry stakeholders.

professionals, professional organizations, local communities, and government bodies. With industry collaboration, the LEGA-C program was designed to provide faster access to funding and enable outreach to specific geographical regions, settings, and patient populations that are often overlooked. Many of these populations, such as people who use drugs (PWUD), those living in rural communities, or those in low- and middle-income countries (LMICs) with high HCV seroprevalence, have been historically underserved and less engaged in health care, as highlighted by the European Association for the Study of the Liver (EASL)[7]. Furthermore, the LEGA-C program planned networking opportunities for investigators to share their experiences in HCV microelimination, such as the Screening and Linkage to Care Summit, which ran from 2017 to 2022. The LEGA-C program funded 121 investigator-sponsored research and collaborative studies via request-for-proposal programs in 36 countries[8,9]. The request-for-proposal programs were launched among external clinical communities, with clear guidance on project objective expectations and the proposal submission process. In this way, the LEGA-C program established a unique approach to partnership with external investigators that could overcome local barriers to treatment and support independent research.

## Long-term outcomes from the LEGA-C program

Simplified care cascades with easier treatment access are needed to ensure optimal treatment uptake with minimal patient loss to follow-up[10]. The primary benefit of programs such as LEGA-C is their ability to rapidly implement sustainable screening, linkage to care, treatment, and monitoring for people with HCV, wherever they are located (Table 1). In the Balearic Islands, Spain, PWUD who had an active HCV infection and participated in the Hepatitis C Free Balears study were offered access to a decentralized treatment process[11]. Participants were telematically prescribed direct-acting antivirals (DAAs) by a hepatologist, with medication delivered either from a hospital pharmacy or a local addiction center[11]. This decentralized health care model demonstrated a high acceptance rate of the intervention among a patient population that has been historically stigmatized[11]. The model was also implemented across addiction centers on the main islands[11]. A similar LEGA-C—funded outreach program for PWUD in Italy was implemented at 15 regional Services for Dependence (SERDs) and also provided a shuttle service, which was continued by some local community SERDs after study completion[12]. Both studies highlight the successful impact of decentralized care models for marginalized people with HCV infection who often lack access to medical care, with both programs achieving a sustained virologic response (SVR) rate ≥90% at ≥12 weeks posttreatment[11,12]. These studies also demonstrate how LEGA-C funding enabled academic researchers to develop a care model for an often-marginalized population for which care was initially controversial, but is now included in HCV treatment guidelines[7,13]. By extension, these studies offer a framework for similar future partnerships focused on global HCV elimination (Fig. 2).

In LMICs, LEGA-C funding has supported several HCV microelimination operational initiatives, such as the 1-year pilot Uzbekistan Hepatitis Elimination Project that included simultaneous rapid testing for HCV and hepatitis B virus (HBV), training for primary care physicians to treat patients with HCV or HBV without advanced liver disease, and the provision of free or below-market-price treatment[14]. This pilot project led to a subsequent 2-year project and culminated in a presidential decree establishing government funding and resources for HBV/HCV screening, HCV treatment, and HBV vaccination for health care workers[14]. In Pakistan, an HCV microelimination study targeted an endemic district of 40,000 individuals, with field teams visiting households to diagnose and treat participants with HCV infection via monthly follow-up visits[15]. Important findings were the high rates of treatment completion (87%, 1527 of 1758 individuals who had active viremia and started treatment) and SVR (91%, 847 of 933 individuals tested 12 weeks posttreatment)[15]. This study demonstrates the feasibility of simplified, low-cost, community-based operational programs for HCV microelimination in highly endemic regions of LMICs[15].

Many of the LEGA-C studies generated evidence that has informed policy decisions related to HCV screening, diagnosis, and treatment guidelines. The ERASE-C outreach campaign in Taiwan focused on screening, diagnosis, and on-site group treatment of HCV among patients with uremia on hemodialysis[16]. On-site treatment led to successful HCV microelimination in hemodialysis centers and provided evidence supporting the safety, efficacy, and effectiveness of DAAs[16], ultimately leading to updated practice guidelines[16,17]. Another outreach campaign for an HCV-hyperendemic community in Taiwan demonstrated the effectiveness of decentralized, on-site screening and treatment in improving HCV care cascade outcomes, even amidst the challenges posed by the COVID-19 pandemic[18]. Emphasizing the decentralization of care to lower-level facilities and task-sharing with non-specialist providers—core principles of international societies—has enhanced the impact on HCV elimination by improving access to care[19–21].

Another advancement to guidelines came through the minimal monitoring (MINMON) study, a collaborative global effort with the AIDS Clinical Trials Group (A5360). This study demonstrated that minimal monitoring and reduced time to treatment initiation have the potential to accelerate HCV elimination[22]. The interventional study of treatment with sofosbuvir and velpatasvir for 12 weeks applied a 4-component approach: (1) no pretreatment genotyping, (2) dispensing the entire treatment course at study entry, (3) no scheduled visits or laboratory monitoring, and (4) two points of remote contact (one at week 4 for adherence, and another at week 22 to schedule an assessment of SVR at week 24)[22]. The results highlighted that with DAAs, the full HCV treatment course can be delivered and completed safely without on-treatment monitoring, and this approach is now recommended in both the American Association for the Study of the Liver and EASL guidelines[7,22,23].

**Table 1 | Selected studies to represent industry and non-industry partners that focus on programs for HCV elimination**

| Publication | Number of citations | Study type | Special populations | Number of participants | | | Treatment | Screening facilities | Treatment Facilities | Outcome |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Screened | HCV RNA+ | Treated | | | | |
| Herranz Mochales A, et al. Implementing a new HCV model of care for people who use drugs. *JHEP Rep*. 2024;6(10):101145. | 4 | SLTC | PWUD | 1463 | 170 | 147 | DAAs | Addiction service center, non-governmental organization center, mobile methadone unit, prison | Prescribed telematically and delivered via hospital pharmacy or local addiction center | SVR ≥12: 93% (88/95 participants monitored) |
| Mangia A, et al. Increased hepatitis C virus screening, diagnosis and linkage to care rates among people who use drugs through a patient-centered program from Italy. *United European Gastroenterol J*. 2021;9(10):1109-1118. | 4 | SLTC | PWUD | 1470 | 231 | 226 | Sofosbuvir/velpatasvir | Addiction centers (regional Services for Dependence) with shuttle service | Hospital hepatology unit | SVR12: 99% (217/220 participants monitored) |
| Musabaev E, et al. Viral hepatitis elimination challenges in low- and middle-income countries-Uzbekistan Hepatitis Elimination Program (UHEP). *Liver Int*. 2023;43(4):773-784. | 4 | Test and treat | LMICs | 54,396 | 1610 | 676 | Noncirrhotic: sofosbuvir & daclatasvir Cirrhotic: sofosbuvir/velpatasvir | Polyclinic (health care clinic) | Polyclinic (health care clinic) | SVR12: 97% (among 63 randomly selected treated participants) |
| Hamid, S, et al. Final results of a hepatitis C micro-elimination campaign in a highly endemic, well-defined demographic area of peri-urban Karachi, Pakistan. Poster presented at: European Association for the Study of the Liver; Jun 21–24, 2023; Vienna, Austria. | 0 | Test and treat | LMICs | 40,148 | 1967 | 1748 | Sofosbuvir/daclatasvir | Door-to-door | Primary care clinic | SVR12: 91% (847/933 participants monitored) |
| Yu ML, et al. Establishment of an outreach, grouping healthcare system to achieve microelimination of HCV for uremic patients in hemodialysis centers (ERASE-C). *Gut*. 2021;70(12):2349-2358. | 32[a] | Test and treat, SLTC | Individuals with HCV and uremia on hemodialysis | 2323 | 174 | 146 | Link-to-care treatment in nearby hospitals: DAAs On-site treatment: sofosbuvir/velpatasvir | Participating hemodialysis centers | Hospitals or on-site participating hemodialysis centers | Link-to-care treatment in nearby hospitals, SVR12: 93% (38/41 participants who started treatment); On-site treatment, SVR12: 90% (94/105 participants who started treatment) |
| Solomon SS, et al. A minimal monitoring approach for the treatment of hepatitis C virus infection (ACTG A5360 [MINMON]): a phase 4, open-label, single-arm trial. *Lancet Gastroenterol Hepatol*. 2022;7(4):307-317. | 69[a] | Minimal monitoring | Global population | 508 | 400 | 399 | Sofosbuvir/velpatasvir | ACTG infectious disease clinic (health care clinic) | ACTG infectious disease clinic (health care clinic) | SVR[b]: 95% (379 of 399 who initiated treatment) |

[a]Citations include updates to clinical practice guidelines.

[b]SVR was combined for a 24-week window starting at least 22 weeks after treatment initiation.

*ACTG* AIDS Clinical Trials Group, *DAA* direct-acting antiviral, *HCV* hepatitis C virus, *LMICs* low- and middle-income countries, *MINMON* minimal monitoring, *PWUD* people who use drugs, *SLTC* screening and linkage to care, *SVR* sustained virologic response, *SVR12* SVR at posttreatment week 12.

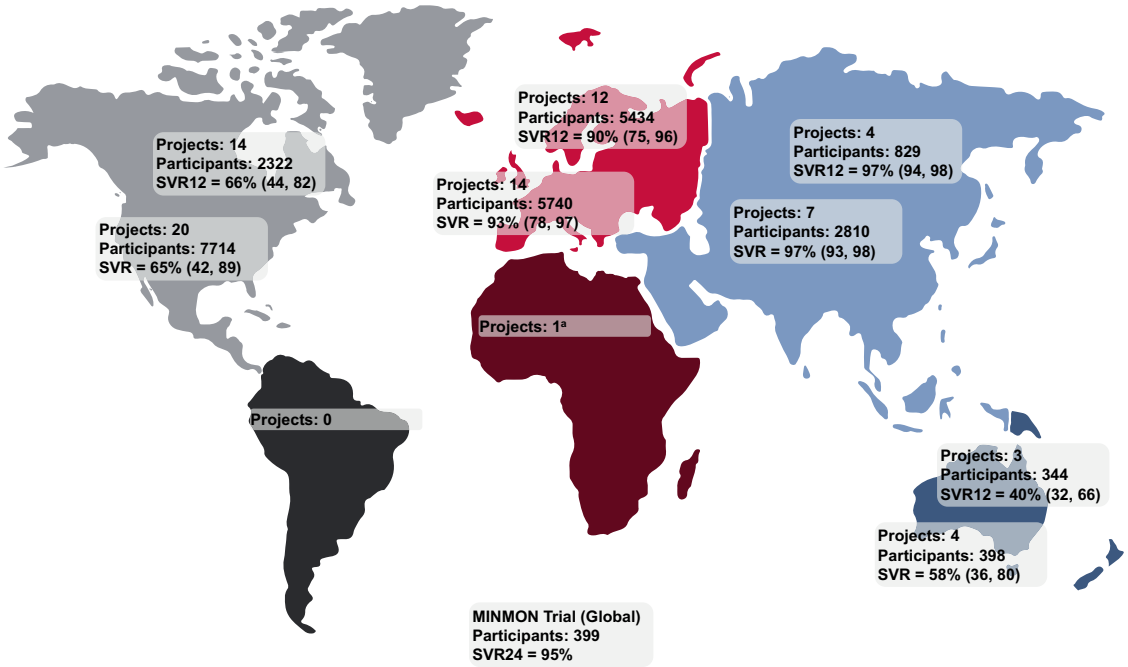


**Fig. 2 | Summary of SVR rates observed across LEGA-C—funded studies on each continent.** Data are shown as the total number of participants monitored for SVR and median (Q1, Q3) SVR12 or SVR across all projects per continent. The time point at which SVR is reported varies by project, with some studies using SVR12 as the primary endpoint, while others report SVR24 or SVR. [a]SVR data not reported. *LEGA-C* local elimination programs leading to global action in HCV, *MINMON* minimal monitoring, *Q* quartile, *SVR* sustained virologic response, *SVR12* SVR at posttreatment week 12, *SVR24* SVR at posttreatment week 24.

## Advancing HCV elimination efforts with nonprofit collaborations

Nonprofit organizations play an important role in sustaining global and local efforts toward HCV elimination. Their contributions include raising awareness about HCV, funding and conducting HCV research, and fostering communication between research, public, and policy stakeholders. These efforts are often crucial to advancing HCV micro-elimination among underrepresented individuals. For example, the Coalition for Global Hepatitis Elimination (CGHE) spearheaded the publication of best practices for hepatitis C linkage to care in pregnant and postpartum women[24] and released recommendations for HCV prevention, testing, and treatment for incarcerated individuals[25]. Nonprofit organizations also host meetings for physicians and researchers to discuss HCV elimination needs with government representatives. Associations Collaborating on Hepatitis to Immunize and Eliminate the Viruses in Europe (ACHIEVE) has held several meetings for EU public health members to meet with physicians and EASL speakers[26]. Likewise, the Alliance for the Elimination of Viral Hepatitis in Spain (AEHVE) hosted Liver Disease Week 2023 and an earlier event in the Spanish parliament, both featuring local physician and policy speakers[27]. These are only a few examples of how nonprofit organizations are essential to connecting stakeholders in the shared goal of HCV elimination. Ongoing engagement with these nonprofit organizations from pharmaceutical companies and academic institutions through funding and strategic relationships is needed to bring HCV awareness and care access to different populations. Through their relationships with global pharmaceutical partners, nonprofit organizations can provide valuable connections to local communities needing additional support to reach HCV elimination goals.

## Enhancing future collaborations toward HCV elimination and beyond

The realized and sustained impact of projects initiated through LEGA-C and nonprofit programs underscores the value of partnerships between industry and non-industry stakeholders. Two of the largest contributions to HCV elimination achieved through LEGA-C were the funding for research that might otherwise have lacked support and the data demonstrating that marginalized populations can adhere to treatment and achieve cure. These successes have brought awareness to the benefits of an HCV micro-elimination approach; future programs like LEGA-C are crucial for advancing local initiatives and addressing other therapeutic areas, such as HIV and metabolic dysfunction-associated steatotic liver disease. Further publication support would enhance the visibility of the research resulting from these collaborations, amplifying the impact of partnerships between industry and non-industry stakeholders. As larger grants become available through these partnerships, investigators will be better equipped to move beyond small proof-of-concept projects and conduct studies that influence government policies and treatment guidelines on a broader scale. The communication networks established via LEGA-C and nonprofit programs facilitated improved knowledge sharing, which was another important component of successful collaboration. Future partnerships targeting HCV elimination and other therapeutic areas should prioritize maintaining these networks beyond the conclusion of partnership studies, as they will be necessary to sustain momentum and drive long-term progress.

## Conclusion

Partnerships between pharmaceutical companies, academic institutes, communities, and nonprofit organizations can play a key role in eliminating HCV and provide lessons for other therapeutic areas. As these partnerships evolve,

it is essential to maintain clear expectations, transparency, and investigator independence throughout the program development process. These collaborations can amplify and enhance local HCV microelimination efforts for at-risk patient populations while aligning researchers toward a shared global goal. Sustained support and flexibility from pharmaceutical companies, for both high-income countries and LMICs, will be important for closing funding gaps and meeting the ongoing treatment needs within the HCV research and medical communities. As domestic and international government aid and research programs face reductions or termination, funding from industry partners will become increasingly essential. Continued partnerships are necessary to generate impactful research that informs treatment guideline updates and drives progress toward HCV elimination by 2030.

## Data availability

No datasets were generated or analysed during the current study.

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Received: 21 March 2025; Accepted: 23 June 2025;
Published online: 03 September 2025

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## Acknowledgements

The LEGA-C program was funded by Gilead Sciences, Inc. Medical writing support was provided by Molly Yeager, PhD, of Red Nucleus, and funded by Gilead Sciences, Inc.

## Author contributions

J.V.L. and N.R. contributed to the conceptualization and writing of the paper. J.V.L., N.R., S.S., A.M., M.L.Y., and H.R. reviewed, edited, and approved the paper.

## Competing interests

N.R. reports grants from AbbVie, Eiger Biopharmaceuticals, Gilead Sciences, Inc., and Salix Pharmaceuticals; consulting fees from Gilead Sciences, Inc., and Salix Pharmaceuticals; and is an advisory board member for Arbutus Biopharma. J.V.L. reports grants and speaker fees from AbbVie, Echosens, Gilead Sciences, Inc., Janssen, Merck Sharp & Dohme, Novo Nordisk, Roche Diagnostics, and ViiV Healthcare, and consulting fees from Echosens, the Global NASH Council, GSK, Novavax, Novo Nordisk, and ProSciento. S.S. reports grants, products, and speaker fees from Gilead Sciences, Inc., and grants and products from Abbott Laboratories. A.M. reports support for attending meetings and/or travel from Gilead Sciences, Inc., and Ipsen; speaker fees from Angelini Pharma, Gilead Sciences, Inc., and Roche; and consulting fees from Akero Therapeutics, Gilead Sciences, Inc., and Madrigal Pharmaceuticals. M.L.Y. reports grants from AbbVie, Bristol Myers Squibb, Gilead Sciences, Inc., Merck, and Roche Diagnostics, and reports consulting and speaker fees for AbbVie, Bristol Myers Squibb, Gilead Sciences, Inc., and Roche. H.R. is a member of advisory boards for AbbVie, Abbott, Gilead Sciences, Inc., Janssen, Merck, Roche, and VBI Vaccines. All proceeds from advisory board participation were donated to the Center for Disease Analysis Foundation. The Center for Disease Analysis Foundation has received research funding from Assembly Biosciences, AbbVie, Boehringer Ingelheim, Gilead Sciences, Inc., Intercept Pharmaceuticals, Merck, Novartis, Pfizer, and Roche.

## Additional information

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