

Update on PITER activities

Maria Giovanna Quaranta

Centro Nazionale per la Salute Globale Istituto Superiore di Sanità

UN PATTO DI COLLABORAZIONE: DALL'ELIMINAZIONE REGIONALE DELL'**EPATITE C** ALLE NUOVE SFIDE PER LA **SALUTE DEL FEGATO**

1 FEBBRAIO 2024 H. 9:00-17:40 RESIDENZIALE + WEBINAR



PITER-HCV Cohort



All HCV-infected patients (any clinical and histopathologic stage of HCV infection, infection by any HCV genotype, HBV, HDV or HIV coinfected patients)

Data collected from 2014 to 2023		N.
Enrolled patients		12.419
	From 2014 to 2016	9.358
	From 2017 to 2023	3.061
Patients with at least 1 follow-up		9.730
Patients with a DAA therapy		7.043
Patients with at least 1 follow-up post therapy		5.614
	Median FU time from the end of treatment	27 months
	Range FU time from the end of treatment	3-101 months
	Patients lost to follow-up	1129
	Deceased patients	203
PITER network Centers		89
	Currently active	50

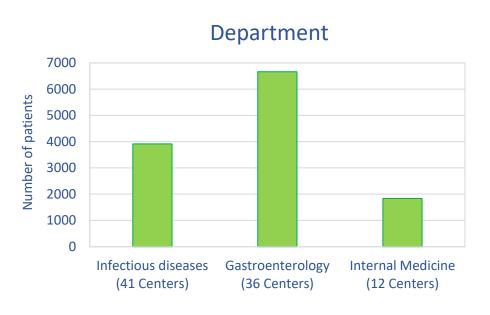
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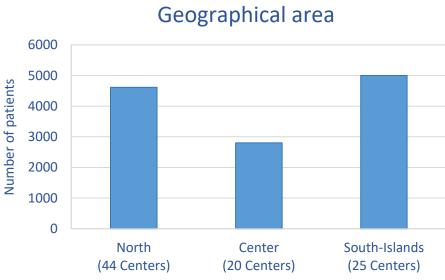
Update of annual follow-up

Update new enrolments to evaluate the epidemiological changes of patients in care in the last years



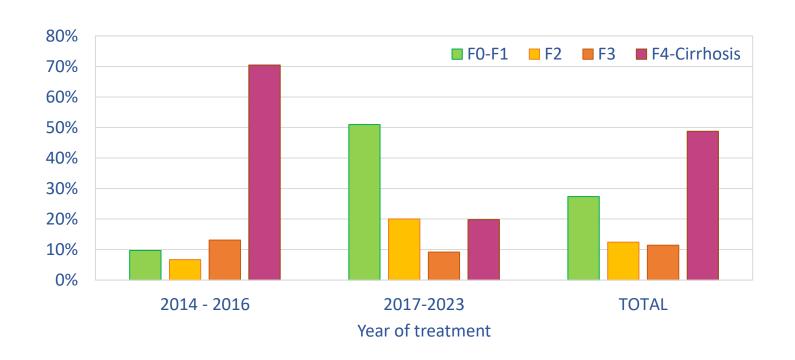
DISTRIBUTION OF PITER NETWORK CLINICAL CENTERS BY DEPARTMENT AND GEOGRAPHICAL AREA







STAGE OF FIBROSIS IN DAA TREATED PATIENTS



Research Article Viral Hepatitis

JOURNAL

Premature ovar

OPLOS ONE

PUBLISH

ABOUT

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RESEARCH ARTICLE

€ OPEN ACCESS ₱ PEER-REVIEWED

HEPATOLOGY

PAASLD

with chronic hepatitis C viral infect

ORIGINAL ARTICLE

HEPATOLOGY HEPATOLOGY, VOL. 66, NO. 6, 2017

Modeling Cost-Effectiveness and Health

Advanced liver disease outco by human im

Hepatology International (2020) 14:362-372

https://doi.org/10.1007/s12072-020-10034-0-

https://doi.org/10.1007/: ORIGINAL RESEA

PharmacoEconomics

Received: 27 July 2021 DOI: 10.1002/hep.32281

Revised: 27 October 2021

Accepted: 8 December 2021

Maria Giovanna Qua Guglielmo Migliorin Liliana Chemello11

ORIGINAL ARTICLE



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Contents lists available at Si

Digestive and Live

journal homepage: www.elsevie

A prospective study of direct-acting antiviral effectiveness and relapse risk in HCV cryoglobulinemic vasculitis by the Italian PITER

Received: 15 August 2023 | Accepted: 19 October 2023 DOI: 10.1002/seg2.12496

ORIGINAL ARTICLE

Liver, Pancreas and Biliary Tract

Clinical features and comorbidity nattern of H compared to na the PITER coho

Maria Giovanna Qu

Marco Massari Ca

Alessia Ciancio^h, Pie

Maurizia Rossana B

Giulia Morsica P. Ga

Loeta A. Kondili 44,

The European Journal of Health Economics https://doi.org/10.1007/s10198-023-01652-0 Loreta A. Kondili1 Laura Gragnani²

Cesare Mazzaro⁵

ueg journal WILEY

ORIGINAL PAPER

Screening strategy to advance HCV elim a cost-consequence analysis

Andrea Marcellusi 100 · Francesco Saverio Mennini 1,2 · Massi collaboration study group

Predicting de-novo portal vein thrombosis after HCV eradication: A long-term competing risk analysis in the ongoing PITER cohort

Loreta A. Kondili^{1,2} | Alberto Zanetto^{3,4} | Maria Giovanna Quaranta¹ | Luigina Ferrigno¹ | Valentina Panetta⁵ | Vincenza Calvaruso⁶ Anna Linda Zignego | Maurizia R. Brunetto | Giovanni Raimondo | Elisa Biliotti Donatella leluzzi Andrea lannone Salvatore Madonia Madonia Liliana Chemello 14 | Luisa Cavalletto 14 | Carmine Coppola 15 Filomena Morisco¹⁶ | Francesco Barbaro¹⁷ | Anna Licata¹⁸ Alessandro Federico 19 | Federica Cerini 20 | Marcello Persico 21 Maurizio Pompili²² | Alessia Ciancio²³ | Fabio Piscaglia²⁴ ○ | Luchino Chessa²⁵ ○ | Andrea Giacometti²⁶ Pietro Invernizzi^{27,28} | Giuseppina Brancaccio²⁹ | Leonardo Baiocchi³¹ | Ivan Gentile³² | Nicola Coppola³³ Antonio Benedetti³⁰ Gerardo Nardone³⁴ | Antonio Craxi⁶ | Francesco Paolo Russo^{3,4} | on behalf of PITER Collaborating Investigators



PITER-HBV/HDV Cohort

All patients with HBsAg positivity for at least 6 months with or without coinfection with HDV and/or HCV and/or HIV who are consecutively observed in the participating clinical centers in a given time span (approximately 6 months), independently of antiviral treatment at the time of enrolment.

Data collected from 2019 to 2023		N.
Enrolled patients from November 2019 to December 2023		5.853
	Anti-HDV screened	4.411
	Anti-HDV positive	507
Patients with at least 1 follow-up		1.739
Participating Centers		63

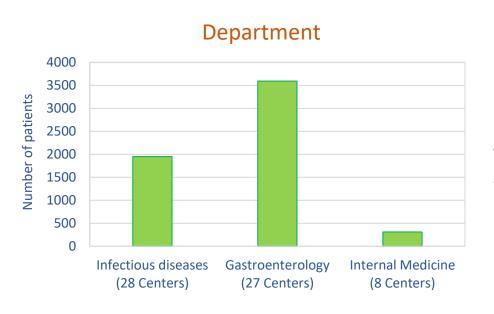
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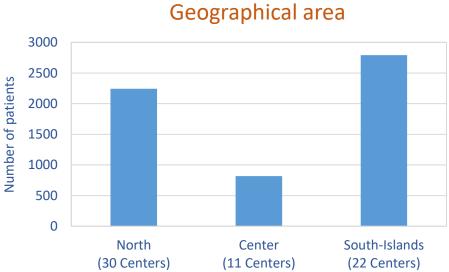
- Enrollment
- Update of annual follow-up



DISTRIBUTION OF PITER NETWORK CLINICAL CENTERS BY DEPARTMENT AND GEOGRAPHICAL AREA

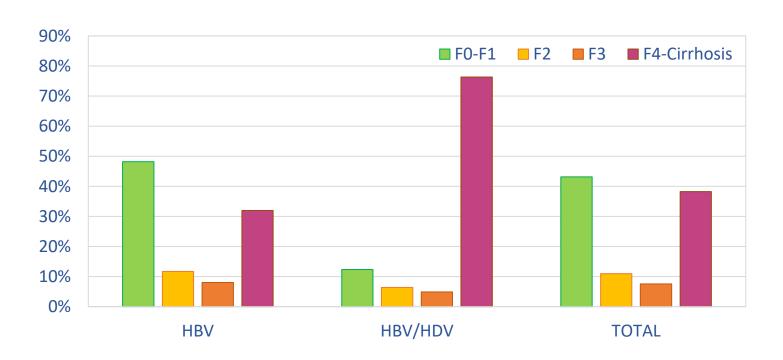








STAGE OF FIBROSIS IN HBV AND HBV/HDV PATIENTS







Contents lists available at ScienceDirect

International Journal of Infectious

journal homepage: www.elsevier.com/locate/lij

Trends in chronic hepatitis B virus infection in Italy period: Clues from the nationwide PITER and MAST elimination

Giuseppina Brancaccio anti, Barbara Coco b.*, Alessandra Nardi c. Mari Maria Elena Tosti d. Luigina Ferrigno d. Irene Cacciola c. Vincenzo M. Filomena Morisco d. Michele Milella f. Francesco Barbaro J. Alessia C. Francesco Paolo Russo J. Nicola Coppola d. Pierluigi Blanc d. Ernesto Gabriella Verucchi d. Massimo Puoti d. Anna Linda Zignego f. Liliana Salvatore Madonia f. Stefano Fagiuoli d. Anna Linda Zignego f. Liliana Salvatore Madonia f. Stefano Fagiuoli d. Antonio Craxì d. Teresa Anto Giovanni Raimondo f. Maurizia R. Brunetto d. Giovanni Battista Gae Loreta A. Kondili d. e. f. PITER collaborating investigators f.

A holistic evaluation of patients with chronic Hepatitis D virus (HDV) infection: Insights from the Italian PITER-B and Delta cohort

Loreta A. Kondili^{1,29}, Giuseppina Brancaccio¹, Maria Elena Tosti¹, Barbura Coco⁴, Maria Giovanna Quaranta¹, Vincenzo Messina¹, Alessia Ciancio², Filomena Morisco², Valentina Cossiga¹, Ernesto Claar², Valerio Rosato⁴, Mariana Ciarallo³, Irene Cacciola¹⁰, Francesca Romana Ponziani¹¹, Lucia Cerrito¹¹, Roberta Coppola¹², Francesco Longobardi¹², Elisa Biliotti¹², Alessia Rianda¹, Francesco Barbaro¹⁴, Nicola Coppola¹⁵, Maria Stanzione¹⁵, Francesco Barbaro¹⁴, Nicola Coppola¹⁵, Maria Stanzione¹⁵, Francesco Barbaro¹⁵, Stefano Fagiuoli¹⁷, Mauro Massari¹⁸, Francesco Paolo Rasso¹⁷, Alberto Ferrarese¹⁰, Diletta Laccabue¹², Vito Di Marco¹², Pierlugi Blanc¹², Aldo Marrone¹⁵, Giulia Morsica¹³, Alessandro Soria¹⁵ Ivana Maida¹¹, Luchino Chessa¹², Michele Milella¹³, Elena Rosselli del Turco¹⁴, Salvatore Madonia¹³, Liliana Chemello¹⁶, Ivan Gentile¹⁷, Pierlugi Tomiuto¹⁶, Masteo Bassetti¹⁸, Lorezzo Surace¹⁶, Leoteardo Baiocchi¹¹, Adriano Pellicelli¹², Adriano De Santis¹⁵, Massimo Puoti¹⁴, Elisabetta Degasperi¹⁵, Grazia Anna Niro¹⁶, Anna Linda Zegnego¹⁷, Antonio Craxi¹⁶, Giovanni Raimondo¹⁶, Teresa Antonia Santannoio, Maurizia Rossana Brunetto¹⁶, Giovanni Battista Gaeta¹⁶⁰ on beltali of PITER Collaboratine Investigatoes¹⁸.

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Research Grants

Gilead Fellowship Program 2022: OTTIMIZZARE LA RETE TRA MEDICO DI MEDICINA GENERALE E CENTRI SPECIALISTICI AL FINE DI SENSIBILIZZARE I PROFESSIONISTI E FORNIRE LORO STRUMENTI PER INCREMENTARE LA DIAGNOSI E L'AWARENESS DEL PAZIENTE CON INFEZIONE DA HBV/HDV

Investigator-Sponsored Research (ISR) Grant Program, Gilead: A PROSPECTIVE

EPIDEMIOLOGICAL, CLINICAL, AND VIROLOGICAL EVALUATION OF AN ONGOING MULTICENTER

REPRESENTATIVE COHORT OF HEPATITIS B VIRUS (HBV)/HEPATITIS DELTA VIRUS COINFECTION

(HDV) IN ITALY

EU4Health Joint Action on Cancer and other NCDs prevention – Action on Health Determinants. WP7 - Social Inequalities - Pilot Sudy: PROSPECTIVE EVALUATION OF THE ROLE

OF SOCIAL DETERMINANTS OF HEALTH IN THE LIVER CANCER PATHWAY IN REPRESENTATIVE

REAL-LIFE MULTICENTER COHORTS IN ITALY



PROPONENT: Anna Linda Zignego

RESEARCH QUESTION: LIVER AND AUTOIMMUNITY IN THE POST-PANDEMIC ERA

BACKGROUND: Autoimmune manifestations, from autoreactivity to organ-specific or systemic

pathologies, have been widely described in Hepatology, both as manifestations in

themselves and as a consequence of hepatitis virus infection, with particular reference to

HCV.

The COVID-19 pandemic has also led to numerous observations that suggest an effect of the latter and related vaccinations on autoimmune diseases. However, this is a debated

topic and further information would be valuable for the purposes of correct F-U and

counseling in cases with a positive anamnesis.

STUDY POPULATION: Consecutive liver diseases of various etiology: viral, post-viral etc. Exclusion criteria: Liver

or other organ transplant patients; Lymphomas or leukemias.



CRF-AUTOIMMUNITY

della Terapia delle Epatiti viRali. Centro: PETTEW SCHOOL OR LESSONATION (MEZIONE COVID 0 6 016 Data (1990) Caratteristichs dell'inflosione Into vieta Prima Infestore Agoio Charto state altre effective eggs to pring? PRINA BEAGNOSE Riscotluzazione di disturbo già cobe Disglobolinamia sintomatita Advisore, multiple VACCINO COVID 0 # Dre izio e ARTES DISTRICT Tigo vecchs School leterals INTERVENTI CHIRURGICI trouts. al One One reta lob din Hote # Cohn Quale (totale 5 righe) nto na ti **Beta intervento** fortis naccemuse 0 Estanção biligra prenerva-Colonyilo minimum providing Hotse if Rept al one one rete Afric genthian PUU 10/03/20 Sede (totale 5 righe) P00 12/03/20 P00 12/03/20 ALTRE INFEZIONE oi o no non noto PRIMA DIAGNOST Rismittenerines di distarbe già noto ANA. Quale (totale 5 righe) AAM. KOPNA: anto-List M DIA pANCA. 2022 O 6 O 74 2023 OIL OIN entrareacterment (s): Alm, specificare Terapia inveseoppressiva in cores: busaggio Data inizio Fitzximeb / 35 Femiliar to per Harattia Automorum ☐ # ☐ 100 ☐ 100k 1000 / B altro, specificare Familianth per Halattis Autoentrorpi O # 10 to 10 to total



PROPONENTS: Marcello Persico, Mario Masarone

RESEARCH QUESTION: LONG TERM IMPACT OF DAA THERAPY ON NATURAL HISTORY OF HCV PATIENTS

WITH DIFFUSE LARGE B CELL LYMPHOMA

BACKGROUND: - The association between NHL and HCV is well known.

- This association is not only epidemiological but also pathophysiological.

- Antiviral therapy for HCV is a well-established treatment for HCV-Related Marginal Zone

and low-grade lymphomas.

- Less is known in DLBCL (High grade lymphomas).

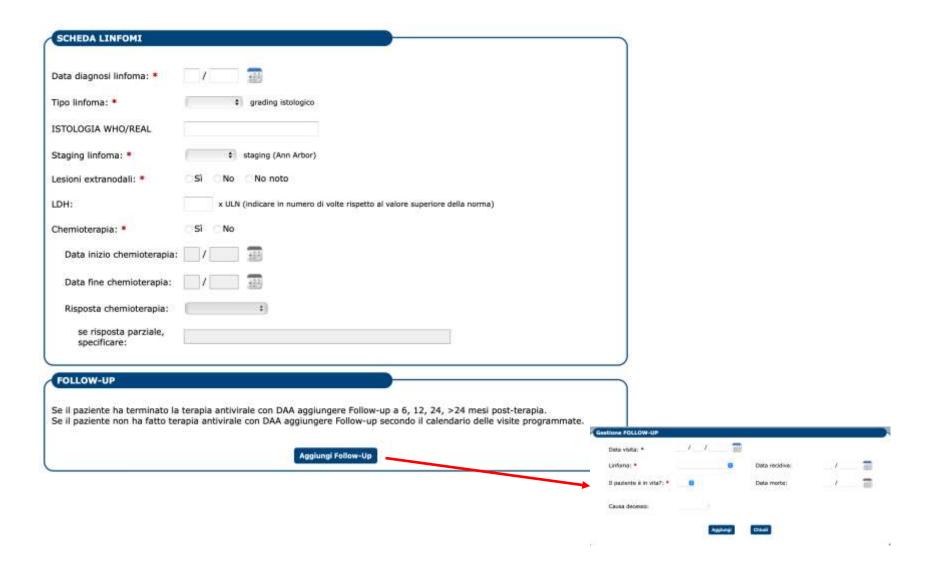
- In 2017 our group published on the significant impact on Disease-free survival (DFS) of a

successful DAA therapy in DLBCL HCV positive patients.

STUDY POPULATION: Patients enrolled in PITER- C Cohort with a reported lymphoma. Estimated n.= 160.



CRF-LYMPHOMA





PROPONENTS: Carlo Torti

RESEARCH QUESTION: WHAT ARE THE RISK OF CLINICAL COMPLICATIONS IN HCV INFECTED PATIENTS WHO

OBTAINED SVR OVER LONG-TERM FOLLOW-UP AND THEIR PREDICTORS?

(PREdictors of EVent After Svr – PRE.EV.A.S. STUDY)

1) To estimate the risk of Hepatic events (such as liver cirrhosis, hepatic failure, HCC) and extra-hepatic complications (in particular cardio-cerebral-vascular events) during long-term follow-up after SVR (considered as baseline);

2) To evaluate the predictors of these events including death for any causes and specific causes. A comparative analysis among non invasive measures for the risk of hepatic and extra-hepatic complications

STUDY POPULATION: DAAs treated patients who achieved SVR enrolled in PITER- C Cohort.

DESIGN and OUTCOMES: All relevant demographic and clinical characteristics at baseline will be collected and analyzed as baseline and time dependent variables, including non invasive indexes (such as APRI, FIB-4, NLR, PLR, PNI, MetS, Charlson Comorbidity Index, FCI, w-FCI).



PROPONENTS: Francesco Paolo Russo, Alberto Zanetto

RESEARCH QUESTION: IMPACT OF HCV ERADICATION ON THE NATURAL HISTORY OF ADVANCED CHRONIC LIVER

DISEASE

To assess the impact of HCV eradication by DAAs on the natural history of compensated

and decompensated cirrhosis.

To identify potential predictors of decompensation (in compensated patients), further

decompensation or recompensation (according to Baveno VII) (in decompensated

patients).

STUDY POPULATION: Cirrhosis DAA treated patients who achieved SVR enrolled in PITER- C Cohort.

OUTCOMES: Decompensation (in compensated patients), further decompensation/recompensation (in

decompensated patients).

NFW PROPOSAL - 5

PROPONENTS: Massimo Colombo

PROPOSAL: COMPARISON BETWEEN TREATMENTS OF HEPATOCELLULAR CARCINOMA AND RISK OF

RECURRENCE

Resection, locoregional therapy, OLT

STUDY POPULATION: Patients who develop de-novo HCC post-SVR enrolled in PITER- C Cohort.



PROPONENTS:

Giulia Morsica, Gianpiero D'Offizi, Massimo Puoti and potential collaboration with ICONA

RESEARCH QUESTION: CLINICAL AND VIROLOGIC FEATURES OF HEPATITIS DELTA VIRUS INFECTION AMONG PEOPLE LIVING OR NOT WITH HIV

- Hepatitis Delta prevalence and clinical course have been mainly studied in HIV negative participants, while, data on HIV-1 positive participants are limited.
- Existing studies suggest that HBV/HDV double infection in people living with HIV is associated with faster progression of liver disease compared to HBV/HDV double infection in people not living with HIV.
- We intend to compare biochemical and clinical features of liver disease as well as virological pattern in people living or not with HIV, with HBV/HDV coinfection.

STUDY POPULATION:

Inclusion criteria: adults with HBV/HDV infection with or without concomitant HIV infection. Exclusion criteria: adults with previous IFN treatment. People living with HIV with less than 200 CD4 cells count. People on treatment with 3TC alone.

OUTCOMES:

Primary end point: To evaluate characteristics of HIV+HBV+/HDV+ vs. HIV- HBV+/HDV+ Secondary end point: To compare clinical and virologic variables possibly associated with advanced liver fibrosis in HIV+HBV+/HDV+ vs. HIV- HBV+/HDV+.



PROPONENTS: Giuseppina Brancaccio, Maurizia Brunetto, Barbara Coco, Giovanni Battista Gaeta,

RESEARCH QUESTION: DIFFERENCES AT DIAGNOSIS OF HEPATOCELLULAR CARCINOMA (HCC) ARISING IN

PATIENTS WITH OR WITHOUT HDV INFECTION

• To describe the clinical and virological characteristics of HCC arising in patients with

chronic HBV infection in relation to the presence of Delta virus (HDV) infection

STUDY POPULATION: Patients with HCC enrolled in the PITER-BD cohort. Estimated n.= 150.

OUTCOMES: Clinical, virological and macro-pathological characteristics.

NEW PROPOSALS - 8

PROPONENTS: Maurizia Brunetto, Giovanni Battista Gaeta, Barbara Coco, Giuseppina Brancaccio

RESEARCH QUESTION: GENDER-ORIENTED ANALYSIS

STUDY POPULATION: Patients enrolled in the PITER-C and PITER-BD cohorts.

OUTCOMES: Epidemiological, Clinical and virological characteristics.

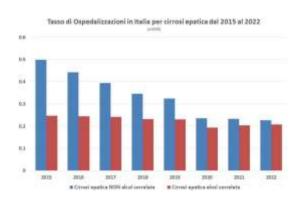


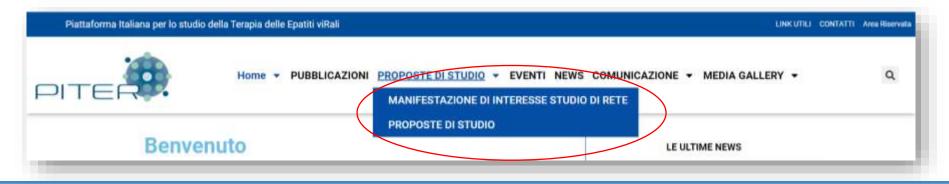
TRENDS IN HOSPITALIZATION FOR ALCOHOLIC AND NON-ALCOHOLIC LIVER CIRRHOSIS AND LIVER CANCER FROM 2012 TO 2022 IN ITALY

PROPONENTS: Stefano Rosato, Paola D'Errigo, Loreta Kondili, Maria Giovanna Quaranta (ISS) Giovanni Baglio (Agenas)



- The study will examine the 10-year trends (2012-2022) of hospitalization rates for alcohol-related and non-alcoholrelated liver cirrhosis, as well as the outcomes of these hospitalizations in terms of both mortality and readmissions.
- Furthermore, the results will be used to evaluate the permanent inclusion of hospitalization indicators for liver cirrhosis in the National Outcomes Program (PNE) currently they are calculated but included in the Sperimental section.





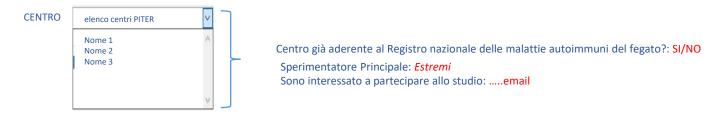
FORM – NUOVA PROPOSTA STUDIO

Centro:	
Sperimer	ntatore Principale:
Propone	nte:
Charling	
Studio:	PITER HCV ^
	PITER HBV/HCV
Titolo:	

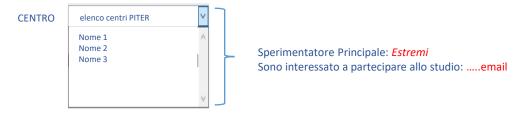
Allega proposta: Allega file

FORM - MANIFESTAZIONE DI INTERESSE PER LE PROPOSTE PRESENTATE

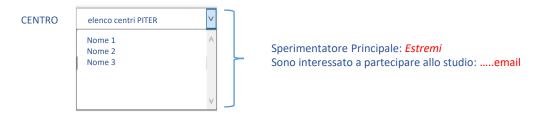
CENTRO PITER INTERESSATO A CONTRIBUIRE AL REGISTRO MALATTIE AUTOIMMUNI DEL FEGATO



CENTRO PITER INTERESSATO A CONTRIBUIRE ALLO STUDIO MASLD



CENTRO PITER INTERESSATO ALLO STUDIO SUI DETERMINANTI DI SALUTE E PROS IN HCC





Collaborazioni





Center for Disease Analysis (CDA) (Colorado USA)
Polaris Observatory





Club Epatologi Ospedalieri (CLEO)



Federazione Italiana degli Operatori dei Dipartimenti e dei Servizi delle Dipendenze (FeDerSerD)



CEIS-EEHTA, Università degli Studi di Roma Tor Vergata



Società Italiana di Medicina Generale e delle cure primarie (SIMG)



Società Italiana di Medicina e Sanità Penitenziaria (SIMSPe)



Società Italiana Patologie da Dipendenza (SIpaD)





Centro Nazionale per la Salute Globale - ISS

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Luigina Ferrigno Maria Elena Tosti Stefano Rosato

Benedetta Mattioli

Loredana Falzano

Franca D'Angelo

Federica Magnani

Rosangela Duranti

Alessandra Mattei

THANK YOU!







Lucia Craxì (Università degli Studi di Palermo)

te Thank you

Dziękuję Ευχαριστώ Kiitos うり難う Obrigado 谢谢 Hvale

Tack תודה Merci Danke Grazie Thank you Gracia

Supporto Informatico (area riservata, CRF)

Area riservata (eCRF): Giampaolo La Terza (Medisoft Servizi Informatici)

Area pubblica: Marco Mirra, Stefano Lucattini, Luca Fucili, Massimilano Di Gregorio (ISS)

Supporto Statistico

Valentina Panetta, Ilaria Simonelli (L'altrastatistica)

Valutazioni economiche a supporto delle politiche sanitarie

Francesco Saverio Mennini, Andrea Marcellusi

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(CEIS -EEHTA)

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