Curriculum vitae

Sara Cresta

TITOLO DI STUDIO :

1999 **Specializzazione in Oncologia** conseguita presso l'Università degli Studi di Milano.

1996 **Abilitazione all'esercizio della professione** conseguita presso l'Università degli Studi di Milano. Iscrizione **Ordine dei Medici di Milano.**

Luglio 1995 **Laurea in Medicina e Chirurgia**, conseguita presso l'Università degli Studi di Milano.

RUOLO ATTUALE:

-**Dal 2002** ***Dirigente Medico*** presso la **SC Oncologia Medica 1**, Fondazione IRCCS Istituto Nazionale dei Tumori di Milano.

-**Dal 2018** incarico di ***Alta Specializzazione*** **di fascia 2** come "*Referente attività clinica di pazienti in ambito di sperimentazione "first in human" e fase I/II con nuovi farmaci"* presso SC Oncologia Medica 1, Fondazione IRCCS Istituto Nazionale dei Tumori di Milano.

PRECEDENTI ESPERIENZE PROFESSIONALI

Durante la formazione universitaria frequenza presso il ***laboratorio di metabolismo intermedio*** e presso la Divisione di *m**edicina interna*** dell'IRCCS **San Raffaele di Milano**.

1996-1997 medico in formazione (Oncologia) presso il ***laboratorio di mutagenesi***, ***IRCCS S. Martino di Genova***.

1997-1999 **medico in formazione** presso l'*Oncologia Medica 1* della Fondazione IRCCS Istituto Nazionale dei Tumori di Milano.

2000 - 2001 **consulente** presso l'*Oncologia* di Multimedica (sede di Castellanza)

2001-2002 **consulente** presso l'*Oncologia Medica 1* della Fondazione IRCCS Istituto Nazionale dei Tumori di Milano

1/6/2018-15/1/2020 ***Responsabile della s.s. Clinical Trials Center*** **e componente del CTQT** per la revisione dei dati di sicurezza dei trials clinici di fase I no profit.

COLLABORAZIONI:

-Dal 2024 ***Referente clinico*** nell'ambito dell'accordo quadro tra la Fondazione IRCCS Istituto Nazionale dei Tumori di Milano e la Fondazione Gianni Bonadonna: "**Concerted Resaerch Institute**" project.

ATTIVITA' CLINICA DI RICERCA

-Esperienza pluriennale come "*Principal Investigator*" o "*Sub Investigator*" di *studi clinici di FASE I/Ib/II in tumori solidi*, *studi retrospettivi e prospettici* inerenti la *patologia mammaria* (progetto TALENT).

Coinvolgimento nei seguenti studi clinici sperimentali:

PI/ SUB-I	Studio clinico
PI	Determination of Caelyx and RAD001 dose in patients with advanced solid tumors
PI	A Phase Ib, Open-Label, Dose-Escalation Study of the Safety and Pharmacology of PI3-Kinase Inhibitor GDC-0941 (Pictilisib) in Combination With Paclitaxel, With and Without Bevacizumab or Trastuzumab, and With Letrozole in Patients With Locally Recurrent Or Metastatic Breast Cancer
PI	A phase I/II study to determine the optimal dose of trabectedin and cisplatin combianation in patients with advanced solid tumors
PI	A phase I, multicenter, open-label, study to evaluate the safety, tolerability and pharmacology of AZD2281 in combination with liposomal doxorubicin (Caelyx®) in patients with advanced solid tumors
PI	Phase I study, dose escalation, for the evaluation of the safety and tolerability of PankoMab-GEX tm in patients suffering from advanced solid tumors, TA-MUC1-positive, no longer treatable with standard therapy
PI	Dose-escalation-, PK- and safety study with single agent CetuGEXTM in patients with EGFR positive locally advanced and/or metastatic cancer
PI	AN OPEN-LABEL, RANDOMISED PHASE 1B/2 STUDY OF PF-04691502 IN COMBINATION WITH LETROZOLE COMPARED WITH LETROZOLE ALONE IN PATIENTS WITH ESTROGEN RECEPTOR POSITIVE, HER-2 NEGATIVE EARLY BREAST CANCER
PI	A phase I, multicenter, open-label, dose-escalation, study of LJM716 administered intravenously in combination with trastuzumab in patients with HER2-overexpressing metastatic breast cancer or gastric cancer
PI	Hepatic chemoembolization in metastatic breast cancer
PI	Expression of NY-ESO-1, PD1-L, microRNA profile (especially expression of miR-205 and miR-9) in primary and metastatic Triple Negative breast cancer
PI	Pilot study for the identification of miRNAs predictive of response to chemotherapy treatment with gemcitabine in metastatic breast cancer
PI	Modulation of the Immune System and Adjuvant Chemotherapy in breast cancer
PI	Circulating microRNAs and sensitivity to gemcitabine in patients with stage IV breast cancer
PI	Retrospective review of ALK and ROS1 expression in solid tumors
PI	A PHASE Ib/II, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER STUDY EVALUATING THE SAFETY, TOLERABILITY, PHARMACOKINETICS, AND EFFICACY OF VENETOCLAX IN COMBINATION WITH TRASTUZUMAB EMTANSINE IN PATIENTS WITH PREVIOUSLY TREATED HER2-POSITIVE LOCALLY ADVANCED OR METASTATIC BREAST CANCER
PI	MasterKey-01: A Phase 1/2, Open-label, Two-part, Multicenter Study to Assess the Safety, Tolerability, Pharmacokinetics, and Antitumor Activity of BDTX-189, an Inhibitor of Allosteric ErbB Mutations, in Patients with Advanced Solid Malignancies
PI	A Phase 1/2 Study of the Selective Anaplastic Lymphoma Kinase (ALK) Inhibitor NVL-655 in Patients with Advanced NSCLC and Other Solid Tumors (ALKOVE-1)
PI	An adaptive first-in-human trial of PhOx430, a first-in-class acetylglucosaminyltransferase V inhibitor, in patients with Advanced Solid Tumours (PhAST Trial)
PI	A Phase 1, Open-Label, Multicenter Study of INCB161734 in Participants With Advanced or Metastatic Solid Tumors With KRAS G12D Mutation
PI	Study of RMC-6291, With or Without RMC-6236, in Combination With Other Anti-Cancer Agents, in Patients With RAS G12C-Mutated Non-Small Cell Lung Cancer – Subprotocol A
PI	A Phase 1b/2 Open-Label, Multicenter Study of RMC-6236 in Combination with Pembrolizumab with or without Chemotherapy, in Patients with RAS-Mutated Non-Small Cell Lung Cancer (NSCLC) – Subprotocol B
SUB-I	Phase *study to evaluate the* pharmacokinetic and pharmacodynamic of PF-03446962 in patients with advanced solid tumors
SUB-I	Phase I dose-escalation study of oral (po) administration of S 78454 (HDACi) in combination with folfox, in patients with locally advanced or metastatic tumors of the digestive tract
SUB-I	A phase I, multicenter, open-label study to evaluate the pharmacokinetics of TKI258 in adult cancer patients with normal or impaired liver function
SUB-I	Phase I study with RXDX-101 in adult patients with advanced/metastatic solid tumors
SUB/I	A phase I, mMulticenter, open-label, dose-escalation study of orally administered LDE225 in combination with BKM120 in patients with advanced solid tumors

SUB-I	Phase Ia/Ib, multicenter, open-label, dose-finding study to evaluate the safety, tolerability, pharmacokinetics and preliminary efficacy data of the pleiotropic modulator CC-122 administered orally to subjects with advanced solid tumors, Non-Hodgkin's Lymphoma or Multiple Myeloma
SUB-I	Phase Ib study of the tumor-targeting human L19TNFα monoclonal antibody-cytokine fusion protein in combination with doxorubicin in patients with advanced solid tumors
SUB-I	A Phase I open-label dose escalation study with expansion to assess the safety and tolerability of INC280 in patients with c-MET dependent advanced solid tumors
SUB-I	Phase IB/II, open-label, multicenter study of orally administered INC280 in combination with gefitinib in adult patients with EGFR-mutated, c-MET-amplified non-small cell lung cancer who progressed after treatment with a gefitinib inhibitor
SUB-I	Open-label phase I dose-finding study of BI 860585 administered orally in a continuous dosing schedule as monotherapy or in combination with exemestane or paclitaxel in patients with various advanced and/or metastatic solid tumors
SUB-I	A first-in-human, dose-escalation pharmacokinetic and pharmacodynamic study to evaluate SAR 125844 administered as a single agent in slow intravenous infusion in adult patients with advanced solid tumors
SUB-I	A Phase 1/2, Open-label Study of Nivolumab Monotherapy or Nivolumab combined with Ipilimumab in Subjects with Advanced or Metastatic Solid Tumors
SUB-I	Phase IB Study of Pembrolizumab (MK-3475) in Subjects with Select Advanced Solid Tumors
SUB-I	A Phase I, Open-label, Multi-center, Dose Escalation Study of Oral BGJ398, a Pan FGF-R Kinase Inhibitor, in Adult Patients With Advanced Solid Malignancies
SUB-I	A phase Ib/II multi-center, open label, dose escalation study of WNT974, LGX818 and cetuximab in patients with BRAFV600-mutant KRAS wild-type metastatic colorectal cancer harboring Wnt pathway mutations
SUB-I	A Phase 1 Multi-center, Open-label Dose Escalation and Expansion Study of PCA062 Administered Intravenously in Adult Patients With p-CAD Positive Tumors
SUB-I	A Phase I, Multi-center, Open Label, Drug-drug Interaction Study to Assess the Effect of Ceritinib on the Pharmacokinetics of Warfarin and Midazolam Administered as a Two-drug Cocktail in Patients With ALK-positive Advanced Tumors Including Non-small Cell Lung Cancer (NSCLC)
SUB-I	An Open-Label, Multicohort, Phase II Study of Atezolizumab in Advanced Solid Tumors
SUB-I	A Multi-center, Open-label Study to Assess the Safety and Efficacy of Combination Ceritinib (LDK378) and Nivolumab in Adult Patients With Anaplastic Lymphoma Kinase (ALK)-Positive Non-small Cell Lung Cancer (NSCLC)
SUB-I	A Phase I/II, Open Label, Multicenter Study of the Safety and Efficacy of LAG525 Single Agent and in Combination With PDR001 Administered to Patients With Advanced Malignancies
SUB-I	An Open-Label, Multicenter, Global Phase 2 Basket Study of Entrectinib for the Treatment of Patients With Locally Advanced or Metastatic Solid Tumors That Harbor NTRK1/2/3, ROS1, or ALK Gene Rearrangements
SUB-I	A Phase I/Ib, Open Label Study of LSZ102 Single Agent and LSZ102 in Combination With Either LEE011 (LSZ102 + LEE011) or BYL719 (LSZ102 + BYL719) in Patients With Advanced or Metastatic ER+ Breast Cancer Who Have Progressed After Endocrine Therapy
SUB-I	A Study of Safety, Tolerability, and Clinical Activity of Durvalumab and Tremelimumab Administered as Monotherapy, or Durvalumab in Combination With Tremelimumab or Bevacizumab in Subjects With Advanced Hepatocellular Carcinoma
SUB-I	A Phase Ib/II, Open Label, Multicenter Study of MCS110 in Combination With PDR001 in Patients With Advanced Malignancies
SUB-I	Open-label Phase 2 Study Evaluating Efficacy and Safety of SAR566658 Treatment in Patients With CA6 Positive Metastatic Triple Negative Breast Cancer
SUB-I	A Phase I/IIa Study of BMS-986148, a Mesothelin Directed Antibody Drug Conjugate, in Subjects With Select Advanced Solid Tumors
SUB-I	A Phase I, Open-label, Multi-center Dose Escalation Study of FAZ053 as Single Agent and in Combination With PDR001 in Adult Patients With Advanced Malignancies
SUB-I	A Phase 1/2a Study of BMS-986205 Administered in Combination With Nivolumab (Anti-PD-1 Monoclonal Antibody) and in Combination With Both Nivolumab and Ipilimumab (Anti-CTLA-4 Monoclonal Antibody) in Advanced Malignant Tumors
SUB-I	A Phase 1/2a Study of BMS-986178 Administered Alone or in Combination With Nivolumab and/or Ipilimumab in Subjects With Advanced Solid Tumors
SUB-I	Phase 1b Multi-indication Study of Anetumab Ravtansine (BAY94-9343) in Patients With Mesothelin Expressing Advanced or Recurrent Malignancies
SUB-I	A PHASE 1/2, OPEN-LABEL, MULTICENTER STUDY OF THE COMBINATION OF NKTR-214 AND NIVOLUMAB OR THE COMBINATION OF NKTR-214, NIVOLUMAB, AND OTHER ANTI CANCER THERAPIES IN PATIENTS WITH SELECT LOCALLY ADVANCED OR METASTATIC SOLID TUMOR MALIGNANCIES
SUB-I	A Phase I/II, Multicenter, Open-label Study of MAK683 in Adult Patients With Advanced Malignancies
SUB-I	A Phase 2, Multi-center, Open Label Study of NIR178 in Combination With PDR001 in Patients With Selected Advanced Solid Tumors and Non-Hodgkin Lymphoma

SUB-I	An International, Multicenter, Phase 1b/2 Study of Rogaratinib (BAY1163877) in Combination With Atezolizumab as First-line Treatment in Cisplatin-ineligible Patients With FGFR-positive Locally Advanced or Metastatic Urothelial Carcinoma
SUB-I	A Randomized, Open-Label, Phase 2 Study of Nivolumab in Combination with Ipilimumab or Nivolumab Monotherapy in Participants with Advanced or Metastatic Solid Tumors of High Tumor Mutational Burden
SUB-I	A Phase 1 Dose Escalation and Cohort Expansion Study of TSR-042, an anti-PD-1 Monoclonal Antibody, in Patients with Advanced Solid Tumors
SUB-I	A Phase 1/2 Study of Oral Selpercatinib (LOXO-292) in Patients With Advanced Solid Tumors, Including RET Fusion-Positive Solid Tumors, Medullary Thyroid Cancer, and Other Tumors With RET Activation (LIBRETTO-001)
SUB-I	A Phase Ib, Open-label, Multicenter Study of Oral LXH254-centric Combinations in Adult Patients With Advanced or Metastatic KRAS or BRAF Mutant Non-Small Cell Lung Cancer or NRAS Mutant Melanoma
SUB-I	A PHASE 2 STUDY TO EVALUATE SAFETY AND ANTI-TUMOR ACTIVITY OF AVELUMAB IN COMBINATION WITH TALAZOPARIB IN PATIENTS WITH BRCA OR ATM MUTANT TUMORS
SUB-I	Phase Ib Study of Gevokizumab in Combination With Standard of Care Anti-cancer Therapies in Patients With Metastatic Colorectal Cancer, Gastroesophageal Cancer and Renal Cell Carcinoma
SUB-I	PHASE Ib, OPEN-LABEL, MULTICENTER STUDY EVALUATING THE SAFETY AND EFFICACY OF IPATASERTIB IN COMBINATION WITH RUCAPARIB IN PATIENTS WITH ADVANCED BREAST, OVARIAN, OR PROSTATE CANCER
SUB-I	An open-label, multi-center rollover protocol for continued characterization of safety and tolerability for subjects who have participated in a Novartis-sponsored spartalizumab study as single agent or in combination with other study treatments
SUB-I	A Phase I Dose Finding Study of Oral LXH254 in Adult Patients With Advanced Solid Tumors Harboring MAPK Pathway Alterations
SUB-I	A Phase 1/2, open-label, multi-center study of the safety and efficacy of KY1044 as single agent and in combination with anti-PD-L1 (atezolizumab) in adult patients with selected advanced malignancies
SUB-I	AN OPEN LABEL, MULTICENTER EXTENSION STUDY IN PATIENTS PREVIOUSLY ENROLLED IN A GENENTECH AND/OR F. HOFFMANN-LA ROCHE LTD SPONSORED ATEZOLIZUMAB STUDY (IMBRELLA B)
SUB-I	A Phase 1/1b first-in-human dose escalation and expansion study for the evaluation of safety, pharmacokinetics, pharmacodynamics and anti-tumor activity of SAR439459 administered intravenously as monotherapy and in combination with cemiplimab in adult patients with advanced solid tumors
SUB-I	A phase I/Ib, open-label, multi-center, study of KAZ954 as a single agent and in combination with Spartalizumab, NZV930 and NIR178 in patients with advanced solid tumors
SUB-I	A Phase I Dose Escalation Study Evaluating the Safety and Tolerability of PF-06804103 in Patients With Human Epidermal Growth Factor Receptor 2 (HER2) Positive and Negative Solid Tumors
SUB-I	A Phase 1 Study Exploring the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of INCB086550 in Participants With Advanced Solid Tumors
SUB-I	A MULTI-CENTER EXPANDED ACCESS PROGRAM (EAP) FOR THE TREATMENT OF PATIENTS WITH LOCALLY ADVANCED OR METASTATIC SOLID TUMORS WITH REARRANGED DURING TRANSFECTION (RET) ACTIVATION (LIBRETTO-201)
SUB-I	A Phase Ib/II Open-label, Multi-center Dose Escalation Study of JDQ443 in Patients With Advanced Solid Tumors Harboring the KRAS G12C Mutation
SUB-I	A Phase 1/2 Study to Investigate the Safety, Pharmacokinetics and Efficacy of Tinostamustine, a First-in-Class Alkylating Histone Deacetylase Inhibition (HDACi) Fusion Molecule, in Patients with Advanced Solid Tumors
SUB-I	A PHASE I/Ib GLOBAL, MULTICENTER, OPEN-LABEL UMBRELLA STUDY EVALUATING THE SAFETY AND EFFICACY OF TARGETED THERAPIES IN SUBPOPULATIONS OF PATIENTS WITH METASTATIC COLORECTAL CANCER (INTRINSIC)
SUB-I	A Phase Ib Multicenter, Open-label Study to Evaluate the Safety and Tolerability of Trastuzumab Deruxtecan (T-DXd) and Immunotherapy Agents With and Without Chemotherapy Agents in First-line Treatment of Patients With Advanced or Metastatic Non-squamous Non-small Cell Lung Cancer (NSCLC) and Human Epidermal Growth Factor Receptor 2 (HER2) Overexpression (OE) (DESTINY-Lung03)
SUB-I	A Phase I/Ib, open-label, multi-center study of DFF332 as a single agent and in combination with Everolimus or IO agents in patients with advanced/relapsed ccRCC and other malignancies with HIF2α stabilizing mutations
SUB-I	A Phase 1/2 Study of BMS-986340 as Monotherapy and in Combination With Nivolumab or Docetaxel in Participants With Advanced Solid Tumors
SUB-I	A single-arm, open-label, multicenter phase 2 study to evaluate the efficacy and safety of taletrectinib in patients with advanced or metastatic ros1 positive nsclc and other solid tumor
SUB-I	AN OPEN-LABEL STUDY FOR CONTINUED TREATMENT ACCESS FOR PARTICIPANTS FROM THE B9991032 AVELUMAB STUDY
SUB-I	An Open-label, Phase 1b, Dose Escalation and Expansion Study to Evaluate the Safety, Tolerability, Maximum Tolerated or Administered Dose, Pharmacokinetics, Pharmacodynamics and Efficacy of the Aryl

	Hydrocarbon Receptor Inhibitor (AhRi) BAY 2416964 in Combination With Pembrolizumab in Participants With Advanced Solid Tumors
SUB-I	Phase I/II Multicenter Study of the Safety, Pharmacokinetics, and Preliminary Efficacy of APL-101 in Subjects with Non-Small Cell Lung Cancer with c-Met Exon 14 Skip Mutations and c Met Dysregulation Advanced Solid Tumors
SUB-I	A Phase 1, Open-Label, Multicenter Study of INCB123667 as Monotherapy in Participants With Selected Advanced Solid Tumors
SUB-I	A Phase 1/2 Study of PBI-200 in Subjects with NTRK-Fusion-Positive Advanced or Metastatic Solid Tumors
SUB-I	A phase I/Ib, open label, multi-center, study of QEQ278 in patients with advanced solid tumor
SUB-I	Phase 1-2 Study Investigating Safety, Tolerability, Pharmacokinetics and Preliminary Antitumor Activity of Various Combinations of BGB-A425 and LBL-007 with Tislelizumab in Patients with Advanced Solid Tumors
SUB-I	A phase I study to evaluate safety and early signs of efficacy of the human monoclonal antibody-cytokine fusion protein IL12-L19L19
SUB-I	A PHASE Ia/Ib, OPEN-LABEL, MULTICENTER, GLOBAL, DOSE-ESCALATION STUDY TO EVALUATE THE SAFETY AND PHARMACOKINETICS OF XmAb24306 AS A SINGLE AGENT AND IN COMBINATION WITH ATEZOLIZUMAB IN PATIENTS WITH LOCALLY ADVANCED OR METASTATIC SOLID TUMORS
SUB-I	A Phase 1, Open-Label, Multicenter Study of INCA33890 in Participants With Advanced or Metastatic Solid Tumors
SUB-I	A Phase 1/2 Study to Evaluate the Safety, Pharmacokinetics, and Efficacy of BLU-222 as a Single Agent and in Combination Therapy for Patients with Advanced Solid Tumors
SUB-I	A Phase I, open label, multi-center study of KFA115 as a single agent and in combination with Tislelizumab in patient with select advanced cancer
SUB-I	An open-label, multi-center, Phase I study of oral IAG933 in adult patients with advanced Mesothelioma and other solid tumors
SUB-I	IL Believe: A Phase 1/2, Open-label, Dose Escalation and Dose Expansion Study to Investigate the Safety and Tolerability of TransCon IL-2 β/γ Alone or in Combination with Pembrolizumab, Standard of Care Chemotherapy, or TransCon TLR7/8 Agonist, or in Combination with Pembrolizumab and Standard of Care Chemotherapy, in Adult Participants with Locally Advanced or Metastatic Solid Tumor Malignancies
SUB-I	A Phase 1/2 Open-label, Multicenter Study to Assess the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of PC14586 in Patients with Locally Advanced or and Efficacy of PC14586 in Patients with Locally Advanced or Metastatic Solid Tumors Harboring a TP53 Y220C Mutation (PYNNACLE)
SUB-I	A Phase 1/2 Study of the Highly Selective ROS1 Inhibitor NVL-520 in Patients with Advanced NSCLC and Other Solid Tumors (ARROS-1)
SUB-I	A Phase 1b Study Evaluating the Safety,Tolerability, Pharmacokinetics, and Efficacy ofAMG 193 in Combination with mFOLFIRINOX orwith Gemcitabine and Nab-paclitaxel in Subjectswith Locally Advanced or Metastatic PancreaticDuctal Adenocarcinoma (PDAC) withHomozygous MTAP-deletion
SUB-I	A Multicenter, Open-label, Phase 1a/1b Study to Investigate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Preliminary Antitumor Activity of BGB B3227 as Monotherapy and in Combination With Tislelizumab in Patients With Advanced or Metastatic Solid Tumors)
SUB-I	Phase II Combination Study of NMS-01940153E and Atezolizumab with or without a prior priming with low dose decitabine for the Treatment of Adult Patients with Unresectable Hepatocellular Carcinoma (HCC) Previously Treated with Immune Checkpoint Inhibitors
SUB-I	A Phase 1b Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Efficacy of AMG 193 in Combination With Carboplatin, Pemetrexed and Pembrolizumab; With Carboplatin, Paclitaxel and Pembrolizumab; or With Pembrolizumab in Subjects With Advanced Non-small Cell Lung Cancer (NSCLC) With Homozygous MTAP-deletion (Subprotocol A)

CORSI DI FORMAZIONE NEL SETTORE DELLE EMERGENZE

- ADVANCED LIFE SUPPORT: 2022
- REFRESH BLS-D: 2024

FORMAZIONE IN MATERIA DI SPERIMENTAZIONE CLINICA

- training GCP: 2024
- aggiornamento continuo sugli studi di fase I: annualmente

EDUCAZIONE CONTINUA IN MEDICINA - ECM

- in regola con i requisiti previsti in materia di "obbligo formativo triennio 2020-2022"
- in corso la formazione per il triennio 2023-2025

Membro ESMO, AIOM

Milano 25/9/2025