An Asia - Pacific Cell Therapy Conference & Hands-on Workshop Series

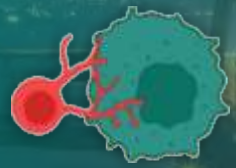
1st - 3rd February 2024, Mumbai

ORGANIZED BY

CAR-T & Cell Therapy Centre (CTCTC), ACTREC, Tata Memorial Centre, Mumbai

3rd SACT EVENT

SACT-2024



Series On Advancements in Cell Therapy

Accelerate the Path to New Cell Therapies in India

BROCHURE & ABSTRACT BOOK

Venue: CIDCO Exhibition Centre, Navi Mumbai

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CAR-T & Cell Therapy Centre (CTCTC), ACTREC,
Tata Memorial Centre, Mumbai

Convener

Dr. Navin Khattry

Deputy Director,
Clinical Research Centre, ACTREC,
Tata Memorial Centre, Mumbai

Founder & Chairman of the Scientific Committee

Dr. (Surg Cdr) Gaurav Narula

Professor Paediatric Oncology & Health Sciences
Project Lead & Principal Investigator
CAR T Cell Therapy Centre
Tata Memorial Centre, Mumbai

Founder & Organizing Secretary

Dr. Albeena Nisar

Senior Lead, R&D and CMC,
Scientific Officer D
Principal Investigator OiVT Project
CAR T & Cell Therapy Centre ACTREC,
Tata Memorial Centre, Mumbai

3rd SACT EVENT

WELCOME TO SACT EVENT

Message From Program Directors

We are excited to announce the upcoming event, Cell Therapy International Conference & Workshop Series, 'Series on Advancements in Cell Therapy' (SACT), an activity of the CAR-T & Cell Therapy Centre (CTCTC) at ACTREC, Tata Memorial Centre, that played a pivotal role in bringing India's first Cell-Gene therapy to fruition. This educational activity was first initiated on 6th Jan 2023 to unprecedented responses from the scientific, healthcare, regulatory, industry and patient advocacy communities, that only grew in the second event on 29-30 Sept 2023, so much that within a year, and now in its 3rd edition it has become the defining Cell & Gene Therapy related event in India and indeed this part of the world.

As you are aware, 'Series on Advancements in Cell Therapy' (SACT), has emerged as a pivotal platform in India, propelling the Cell Therapy Industry to the forefront, garnering global attention for its advancements in new therapies, research and development, and manufacturing in just one year since its inauguration. The inaugural SACT event and its sequel witnessed resounding success, drawing over 280 on-site delegates each and earning positive acclaim from stakeholders in the Cell Therapy community, spanning academia and industry.

Looking ahead, the 3rd SACT, planned for 1st- 3rd February 2024, is envisioned to be one of the largest International Cell Therapy Meetings in the Asia-Pacific Region for 2024, and will subsequently transition into an annual event thereby becoming a steadfast source of education, innovation, networking and collaboration in the field of Cell Therapy in India and the Asia- Pacific Region.

Being the first of its kind in India, an Academic-Industry meeting focused on bridging the gap and facilitating further collaboration, it also presents a compelling opportunity for prospective Cell Therapy investors and companies to not only participate but also cultivate a vested interest in the burgeoning Indian Cell Therapy market.

3rd SACT EVENT

Anticipated highlights include:

- Cell Therapy pioneers as International Speakers & FDA regulatory experts covering 7 different tracks :
  - Discovery & Innovation
  - Manufacturing & CMC
  - Clinical Monitoring & Assessment
  - Investment
  - Commercialization & Market Access
  - Translational
  - Clinical Acceleration
  - Patient Advocacy
  - Regulatory
- Each session contains plenary speakers and panel discussions, which addresses not only the state of the art development in the filed but key challenges & solutions.
- Fire-side Leadership discussions
- Workforce Capacity building Initiative : First of its kind Hands-on training in GMP processes & Clinical Manufacturing
- Fostering opportunities for regional collaborations in academia and industry between India and APAC countries.
- Projected participation of 450+ individuals, representing all aspects of the Cell Therapy space spanning India and all APAC countries, along with the members of the ISCT society, makes it poised to be a convergence of expertise, collaboration, and innovation that will undoubtedly contribute to the advancement of Cell Therapy on a global scale.

We eagerly anticipate the possibility of a fruitful, capacity-building, and mutually beneficial partnership between your company and SACT, contributing to the growth of Cell Therapy in India and creating a lasting impact on the industry. Each one of you joining us today is contributor to the success of this initiative.

Founder & Chairman of the Scientific Committee

Dr. (Surg Cdr) Gaurav Narula
Professor Paediatric Oncology
& Health Sciences Principal
Investigator CAR T Cell Therapy
Centre & Cell Therapy Program
Tata Memorial Centre, HBNI, Mumbai

Founder & Organizing Secretary

Dr. Albeena Nisar
Senior Lead, R&D,
Process Development and CMC
Scientific Officer D
CART & Cell Therapy Centre ACTREC,
Tata Memorial Centre, Mumbai

HIGHLIGHTS

Discovery | Pre-Clinical | Process Development | CMC/ ANALYTICS | CLINICAL TRIAL | LOGISTICS | COMMERCIAL DEVLOPEMENT

- Awards/ Travel sponsorship for Scholars
- 2 Days International Symposium
- Cell Therapy Think Tank
- Hands-on Training in CT & cGMP Processes
- 6 Different Tracks covered in each event
- Rapid Fire Talks /Panel Discussions

SCAN FOR BROCHURE & ABSTRACT BOOK

SCAN FOR AGENDA

Previous SACT events

SACT 1 which was the Inaugural SACT event was held in two sessions: Successes and Challenges of Cellular Immunotherapy and Bridging Cell Therapy Process Development & cGMP Manufacturing which was a huge successfully conducted event and one of a kind in the Asia pacific region in the context of Cell therapy.Moving up from our success in first SACT, our theme for this

SACT 2 conference was to accelerate the path to new cell therapies in India, encapsulating our collective commitment to advancing the field, striving for excellence, and improving the lives of patients through transformative cell-based therapies. The conference was an overall essence which turned out not only to be informative but transformative as well. SACT 2 event was held in a series of 7 different tracks covering – Discovery, Pre-Clinical, Process Development, CMC/Analytics, Clinical Trial, Logistics, & Commercial Development. The 2nd SACT event also witnessed a Run/Walk where all the delegates and faculty gathered for the conference enthusiastically put up their shoes on for raising awareness about Cell Therapy in India. The run/walk was accelerated with the theme #CellsCanRun. The run/walk was a success with the support of ImPaCCT Foundation. Ayaan Hashmi and Parveen Shahani were honorary guests for the event of Run/Walk.

Why you should be attending :

Discover the latest in vivo gene engineering techniques for Design & Development of CAR T products, CAR-NK, and Armoured CTPs for improving tolerability and efficacy

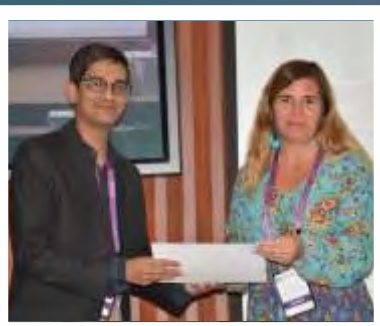
Uncover the potential of combining modalities by leveraging the power of CAR technology across T-cells, NK cells, TILs,

Elevate your GMP workflows, CMC and analytical workstreams to optimize development of safe and high-quality cell therapy products

Achieve success during early phase 1/2 development as seasoned industry experts guide you, understand the regulatory pathway and improvise on Patient Data Monitoring

Who Attends?

- Cell Therapy Academics and Clinicians
- Pharma and Biotech Companies
- Cell Therapy Researchers
- Bioprocess Development
- Product Research and Development
- Cellular Immunotherapy Manufacturing Industries
- Cell Engineering Labs and Organizations
- Novel Vector Systems
- Bioengineering based labs



AT A GLIMPSE

3rd SACT EVENT

SACT 2024

7 Different Tracks

- Discovery & Innovation
- Translational Track
- Manufacturing
- Clinical Acceleration
- Clinical monitoring & assessment
- Regulatory
- Commercialization

Fireside Leadership Discussion

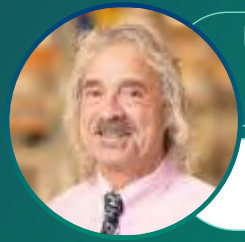
- Patient Advocacy
- Catalyzing Investment

DISCOVERY AND INNOVATION TRACK

Exploring Innovations for Next-generation Cell and Gene Therapies

Dr. Akshay Sharma
St. Jude Children's Research Hospital, USA

Tailored Gene Therapies Targeting Sickle Cell Anaemia



Dr. Wayne A. Marasco
Dr. Wayne A. Marasco
Harvard Medical School,USA

Development of effective Pre-clinical animal models to predict outcomes in Human Trials

Dr. Alok Srivastava
Christian Medical College, Vellore, India

Harnessing Gene Therapy for Hemophilia and the Progress in India

MANUFACTURING TRACK

How to Elevate Early your Process Optimization & Analytics for Faster Approval

Dr. Steven Highfillma
National Cancer Institute, USA

Novel Manufacturing Process: CAR-T cell expansion platforms yield distinct T cell differentiation states

Mr. Srinidhi Deshpande
Cytiva, CCRM, Canada

Buy vs Build Manufacturing- Autologous CAR T Therapy

TRANSLATIONAL TRACK

The Current Landscape of Cell Therapy for Solid Tumours & Beyond

Dr. Khalid Shah
Harvard Medical School, USA

Gene Edited and Engineered Tumor cells: A New Immunotherapeutic Approach for Cancer

Dr. Rajiv Khanna
QIMR Berghofer Medical Research Institute, Australia

Cellular Immunotherapies for Virus-associated Cancers and Post-transplant Infectious Complications

Dr. Avery Posey
Perelman School of Medicine, University of Pennsylvania, USA

Next-generation CARs- Targeting Solid Tumours taking into consideration the Tumour Microenvironment

REGULATORY TRACK

From First in Human to Speeding up to Clinical Trials

Dr. Peter Marks
National Cancer Institute, USA

Regulatory Advice to Guide the Development of the Next Wave of Cell Therapies

CLINICAL TRACK

CAR-T Cells for Hematolymphoid Malignancies

Session 1

Dr. Hasmukh Jain
Tata Memorial Hospital,
Mumbai, India

The Landscape of CD19-directed CAR T Therapies for B- Lymphomas in Adults

Dr. Carlos Fernandez de Larrea
University of Barcelona,
Barcelona, Spain

CAR-T Cells in Multiple Myeloma & Spain's Academic Model for CAR-T Development

Dr. Nirali Shah
National Cancer Institute,
USA

CAR T -cells for Myeloid Malignancies: So Near & Yet So Far

CLINICAL TRACK

Paediatric ALL: The CAR-T Cell Role Model

Session 2

Dr. Stephan A. Grupp
Children's Hospital of
Philadelphia, USA

Building Better CAR T Therapies - Reflections of emergent challenges over a decade of CAR T cell therapy

Dr. Ajay Vora
University of Sheffield,
UK

Replacing chemotherapy with immune therapy in children and young persons with ALL

Dr. Kevin Hay
Terry Fox Laboratory,
Canada

First in Canada CAR-T Cell Therapy- Building Low Cost and Equitable Treatment Capacity

CLINICAL TRACK

Monitoring & Measuring: Maximising Clinical Outcome with CAR-T Cell Therapy

Dr. Gaurav Chatterjee
ACTREC,
Mumbai, India

Monitoring of Circulating CAR T Cells: Validation of a Flow Cytometric Assay, Cellular Kinetics, and Phenotype Analysis

Dr. Nishant Jindal
ACTREC, Mumbai,
India

Third Party Virus Specific T-Cells Post Allogenic Transplant

Dr. Swaminathan Iyer
MD Anderson Cancer Center,
USA

Off the shelf CAR-T approaches for Lymphoma

FIRESIDE LEADERSHIP DISCUSSION

PATIENT ADVOCACY TRACK

Equity, Access & Affordability of Cell Therapies

INVESTMENT & FUNDING OPPORTUNITIES TRACK

Paving the way for the Future of Cell Therapy in India: The Trajectory of Future Investmen

COMMERCIALIZATION TRACK

The Trajectory of Future Investment and Easy Patient Accessibility Mode

SCIENTIFIC PROGRAMME

3rd

SACT 2024
SCIENTIFIC
AGENDA

3rd SACT 2024 SCIENTIFIC AGENDA

Friday, 2nd February 2024

Time	Programme
08:30 - 09 : 15	**Registration & Welcome Coffee**

DISCOVERY AND INNOVATION TRACK
Exploring innovations for Next-generation Cell and Gene Therapies
Chairperson:
Dr. Navin Khattry, ACTREC, TMC & **Dr. Jyoti Anand Kode,** ACTREC, Tata Memorial Centre .

Time	Title	Speaker
9:15 - 9:40	Tailored Gene Therapies Targeting Sickle Cell Anaemia	**Dr. Akshay Sharma,** St. Jude Children's Research Hospital, USA
9:40 - 10:05	Development of effective Pre-clinical animal models to predict outcomes in Human Trials	**Dr. Wayne A. Marasco** Harvard Medical School, USA
10:05-10:30	Harnessing Gene Therapy for Hemophilia and the Progress in India	**Dr. Alok Srivastava** Christian Medical College, Vellore, India
10:30 - 10:35	**Q & A**	

Fire Side Panel Discussion
Accelerating Innovation-A Roadmap for India
Moderated by-
Dr. Akrasubhra Ghosh, Narayan Nethralaya Eye Hospital

Time	Speaker	Speaker
10:35-11:05	**Dr. Rahul Purwar** IIT Bombay, ImmunoACT, Mumbai, India	**Dr. Raghu Padinjat** National Centre for Biological Sciences (NCBS), Bangalore, India
	Dr. Sivaprakash Ramalingam - Institute of Genomics and Integrative Biology (CSIR), Delhi India	**Dr. Shashwati Basak** Intas Pharmaceuticals, Ahmedabad, India
	Dr. Alok Srivastava Christian Medical College, Vellore, India	
11:05 - 11:20	**Coffee Break**	

3rd SACT 2024 SCIENTIFIC AGENDA

11:20 - 11:45	INAUGURATION CEREMONY	
11:20 - 11:45	Opening Remarks	**Dr. Albeena Nisar**, Organizing Secretary- SACT, ACTREC, TMC
	Welcome Address	**Dr. Navin Khattry,** Deputy Director, CRC, ACTREC, TMC
	Address by the Chairman of Scientific Committee	**Dr. (Surg Cdr) Gaurav Narula,** Chairman of Scientific Committee-SACT
	Remarks	**Dr. Prasanna Venkataraman,** Deputy Director, CRI, Mumbai
	Address by the Chief Guest	**Dr. Jitendra Kumar,** MD, DBT- BIRAC, New Delhi, India
	Vote of Thanks	**Dr. Albeena Nisar**
	Lighting of Lamp & Inauguration	
	Special Address: The Concept of Innovation and Orchestration: "Translating Therapies from Bench to Bedside"	**Dr. Khalid Shah,** Harvard Medical School, USA

Manufacturing Track
How To Elevate Early Your Process Optimization & Analytics For Faster Approval
Chairpersons: Dr. Nirali Shah, NCI & Dr (Lt Col)Pawan Gupta, Stempeutics

Time	Title	Speaker
11:45 - 12:10	Novel Manufacturing Process: CAR-T cell expansion platforms yield distinct T cell differentiation states	**Dr. Steven Highfill** National Cancer Institute, USA
12:10 - 12:35	Buy vs Build Manufacturing- Autologous CAR T Therapy	**Mr. Srinidhi Deshpande** Cytiva, CCRM, Canada
12:35 - 12:40	Q & A	

Fire Side Panel Discussion
Planning Better for Faster Approvals
Moderated by - Dr. Uday Kumar Kolkundkar Stempeutics

Time	Speaker	Speaker
12:40 - 13:10	**Dr. Raviraja N. S.** Manipal Academy of Higher Education, Manipal, India.	**Dr. Atharva Karulkar** Co-Founder & Head, Scientific Affairs, ImmunoACT
	Dr.Albeena Nisar Tata Memorial Centre	**Dr. Satya Pavan Kumar Verma Chekuri** Medtherapy Biotechnology, Noida, India
	Dr. Steven Highfill National Cancer Institute, USA	**Mr. Vijaya Kumar Pedinenikaluva** Lupin, India

3rd SACT 2024 SCIENTIFIC AGENDA

13:10 - 13:35	Showcase Presentation- Thermo Fisher Scientific	
Time	**Tittle**	**Speaker**
13:10-13:35	Cell and Gene Therapy Solutions: Recent technical innovations that facilitate manufacturing steps in the CAR-T cell workflow	**Dr. Roland Leathers** Senior Manager, Thermo Fisher Scientific
13:35 - 14:30	**LUNCH & POSTER WALK**	

TRANSLATION TRACK
The current landscape of Cell therapy for Solid Tumors & Beyond
Chairpersons: Dr. Girish Chinaswamy, Tata Memorial Hospital & Dr. Prasanna Venkatraman, ACTREC

Time	Tittle	Speaker
14:30-14:55	Gene Edited and Engineered Tumor cells: A New Immunotherapeutic Approach for Cancer	**Dr. Khalid Shah** Harvard Medical School, USA
14:55 - 15:20	Cellular Immunotherapies for Virus-associated Cancers and Post-transplant Infectious Complications	**Dr. Rajiv Khanna** QIMR Berghofer Medical Research Institute, Australia
15:20 - 15:45	Next-generation CARs- Targeting Solid Tumours taking into consideration the Tumour Microenvironment	**Dr. Avery Posey** Perelman School of Medicine, University of Pennsylvania, USA
15:45 - 15:50	**Q & A**	

Fire Side Panel Discussion
Breaking “Solid” Barriers to Cell/ Gene Therapy
Moderated by: Dr. Albeena Nisar, ACTREC, Tata Memorial Centre

Time	Speaker	Speaker
15:50 - 16:20	**Dr. Shailendra Upraity** Aurigene Pharmaceutical Services Limited, Banglore, India	**Dr. Rajiv Khanna** QIMR Berghofer Medical Research Institute, Australia
	Dr. Khalid Shah Harvard Medical School, USA	**Dr. Rajarshi Pal** Eyestem Research, C-CAMP, Bengaluru, India
	Dr. Vainav Patel NIIRCH, Mumbai, India	**Dr. Avery Posey** Perelman School of Medicine, University of Pennsylvania, USA
16:20-16:30	**Tea Break**	
16:30-16:50	**Oral Poster Presentation**	

3rd SACT 2024 SCIENTIFIC AGENDA

Regulatory TRACK
From First In Human to Speeding up to Clinical Trials
Chairpersons: Dr. Shripad D. Banavali, Tata Memorial Centre & Dr. Stephan Grupp, CHOP, USA

Time	Title	Speaker
16:50-17:15	Regulatory Advice to Guide the Development of the Next Wave of Cell Therapies	**Dr. Peter Marks** Director, Center for Biologics Evaluation & Research (CEBR) FDA

Panel Discussion
Constructing Conducive Regulatory Frameworks for Cell Therapies
Moderated by - Dr. (Lt Col) Pawan Kumar Gupta, Stempeutics Research Pvt Ltd, Bangalore, India

Time	Speaker	Speaker
17:15- 17:45	**Dr. Peter Marks** Director, Centre for Biologics Evaluation & Research (CEBR) FDA, USA	**Dr. Geeta Jotwani** Senior Deputy Director General, ICMR New Delhi, India
	Dr. Subrata Sinha All India Institute of Medical Sciences (AIIMS), New Delhi, India	**Dr. Rajiv Khanna** QIMR Berghofer Medical Research Institute, Australia
	Dr. Yogendra Kumar Gupta AIIMS Bhopal, AIIMS Jammu,Medical Advisor at VaidyaRx,New Delhi, India.	**Dr. Annu Uppal** US Pharmacopeia, Hyderabad, India

Investment & Funding Opportunities Track
Paving the way for the Future of Cell Therapy in India: The Trajectory of Future Investment.
CHAIRPERSON: Dr. Jitendra Kumar, DBT BIRAC, New Delhi, India

Time	Title	Speaker
17:45-18:10	Catalyzing Investments in Cell & Gene therapy Industry	**Dr. Anand Govindaluri** Govin Capital, Singapore

Fire Side Panel Discussion
Fire Side Leadership Panel Discussion
Moderated by Dr. Anand Govindaluri, Govin Capital, Singapore

Time	Speaker	Speaker
18:10-18:40	**Dr. PM Murali** ABLE, Bangalore	**Dr. Saravanabhavan Thangavel** CMC Vellore, India

3rd SACT 2024 SCIENTIFIC AGENDA

18:10-18:40	**Dr. Raj K Shirumalla** National Biopharma Mission, BIRAC, New Delhi, India	**Dr. Mohammad Atif Alam** Centre for Cellular and Molecular Platforms, Bangalore, India
	Dr. Dinesh Kundu East Ocyon Bio Private Limited Gurugram, India.	
19:00 Onwards	**Gala Dinner**	

Saturday, 3rd February 2024 — DAY 2

Time	Programme
08:30 - 9:00	**Coffee/Breakfast**

CLINICAL TRACK
CAR-T Cells for Hematolymphoid Malignancies
Session 1:
Chairpersons:
Dr. Pankaj Malhotra, PGIMER, Chandigarh, India & Dr. Swaminathan Iyer, MD Anderson

Time	Title	Speaker
09:00-09:25	The Landscape of CD19-directed CAR T Therapies for B- Lymphomas in Adults	**Dr. Hasmukh Jain** Tata Memorial Hospital, Mumbai, India
9:25 - 09:50	CAR-T Cells in Multiple Myeloma & Spain's Academic Model for CAR-T Development	**Dr. Carlos Fernandez de Larrea** University of Barcelona, Barcelona, Spain
09:50 - 10:15	CAR T -cells for Myeloid Malignancies: So Near & Yet So Far	**Dr Nirali Shah** National Cancer Institute, USA
10:15-10:20	**Q & A**	
10:20 - 10:35	**Tea/ Coffee break**	

3rd SACT 2024 SCIENTIFIC AGENDA

Session 2 - Paediatric ALL: The CAR-T Cell Role Model
Chairpersons: Dr. Shripad D. Banavali, Tata Memorial Centre &
Dr. Revathi Raj, Apollo Hospitals Cancer Centre Nandanam, Chennai, India

Time	Title	Speaker
10:35 - 10:50	Emily Whitehead- The Story that Sailed Triggered a Cell Therapy Revolution Emily Whitehead Foundation, USA	
10:50-11:15	Building Better CAR T Therapies - Reflections of emergent challenges over a decade of CAR T cell therapy	**Dr. Stephan A. Grupp** Children's Hospital of Philadelphia, USA
11:15-11:40	Replacing chemotherapy with immune therapy in children and young persons with ALL	**Dr Ajay Vora** University of Sheffield, UK
11:40-12:05	First in Canada CAR-T Cell Therapy- Building Low Cost and Equitable Treatment Capacity	**Dr. Kevin Hay Terry** Fox Laboratory, Canada

Fire Side Panel Discussion
Integrating CAR T- Cells into Treatment Algorithms in India- Paving The Road Ahead
Moderated by Dr. Gaurav Narula, Tata Memorial Hospital, TMC

Time	Speaker	Speaker
12:05-12:35	**Dr. Akanksha Chichra** Tata Memorial Centre, Mumbai, India	**Dr.Sharat Damodar** Narayana Health, Bangalore, India
	Dr Bhausaheb Bagal Tata Memorial Hospital, Mumbai, India	**Dr. Nirali Shah** National Cancer Institute, USA
	Dr. Stephan A. Grupp Children's Hospital of Philadelphia, USA	**Dr Ajay Vora** University of Sheffield, UK
12:35 - 13:35	**LUNCH & POSTER WALK**	

Showcase Presentations
Chairperson: Dr. Manoj Mahimkar, ACTREC, Mumbai, India
Dr. Vikaramjit Kanwar, Homi Bhabha Cancer Hospital, Varanasi, India

13:35 - 14:00	Key Learnings from the Scale-Up of Pivotal Trial in DLBCL	**Dr. Anna Wijatyk,** Miltenyi Biomedicine
14:00 - 14:25	Chronicle Automation Software - A GMP Manufacturing Solution for Cell Therapy	**Mr. Chang Teck Ming,** Cytiva

3rd SACT 2024 SCIENTIFIC AGENDA

CLINICAL TRACK
Monitoring & Measuring: Maximising Clinical Outcome with CAR-T Cell Therapy
Chairpersons: Dr. P.G. Subramanian, ACTREC and Dr. Reena Das, PGI Chandigarh

Time	Title	Speaker
14:25-14:50	Monitoring of Circulating CAR T Cells: Validation of a Flow Cytometric Assay, Cellular Kinetics, and Phenotype Analysis	**Dr. Gaurav Chatterjee** ACTREC, Mumbai, India
14:50 - 15:15	Third Party Virus Specific T-Cells Post Allogenic Transplant	**Dr. Nishant Jindal,** ACTREC, Mumbai, India
15:15 - 15:40	Off the shelf CAR-T approaches for Lymphoma	**Dr. Swaminathan Iyer** MD Anderson Cancer Center, USA
15:45 - 15:55	**TEA BREAK**	
15:55 - 16:15	**Oral Poster Presentation**	

Fire Side Panel Discussion
All Tools in One Box
Moderated by Dr. Chetan Dhamne, ACTREC, TMC

Time	Title	Speaker
16:15 - 16:45	**Dr. Pankaj Malhotra** PGIMER, Chandigarh, India	**Dr. Nikhil Patkar** Tata Memorial Centre, Mumbai, INDIA
	Dr. Kevin Hay Terry Fox Laboratory, Canada	**Dr. Sameer Bakhshi** All India Institute of Medical Sciences, New Delhi, INDIA
	Dr. Gaurav Chatterjee ACTREC, Mumbai, India	**Dr. Carlos Fernandez de Larrea** University of Barcelona, Barcelona, Spain

3rd SACT 2024 SCIENTIFIC AGENDA

COMMERCIALIZATION TRACK

The trajectory of future investment and easy patient accessibility mode

Fire Side Panel Discussion

Think Tank-Industry

Moderated by Dr. Anand Govindaluri, Govin Capital, Singapore

Time	Speaker	Speaker
16:45 - 17:15	**Dr. Murali Ramachandra** Aurigene Oncology, Bangalore, India.	**Dr. Mahesh Bhalgat** Syngene International Limited, Bangalore, India
	Mr. Shirish Arya ImmunoACT, Mumbai, India	**Dr. Samir Kulkarni** Institute Of Chemical Technology, Mumbai, India.
	Dr. Jeevan Ghosalkar - Cipla Limited, Mumbai, India	

PATIENT ADVOCACY TRACK

Equity, Access & Affordability of Cell Therapies

Time	Title	Speaker
17:15 - 17:45	Fire Side Panel Discussion with leading Oncologists, Patient Solution Focused Agencies and Patient Advocate groups	*Moderated by* **Ms. Shalini Jatia** Impact Foundation
17:45 - 18:15	**Valedictory**	
	Closing Remarks	

SACT ANNUAL MEETING ASBTRACTS

3rd

SACT 2024 SCIENTIFIC AGENDA

Abstract no. 1
Category: Translational

Title: Exploring the Potential Role of Immune Complexes in Modulating the Efficacy of Dendritic Cell-Based Immunotherapy

Author/s: Ms. Vaishnave Sakthi Prasad
Junior Research Fellow
Cancer Institute (WIA), Chennai, India

Immune complexes (ICs) of tumor-associated antigens and autoantibodies may be beneficial as they also harbor the ability to elicit an immune response. These immune complexes also take part in modulating the immune cell response towards tumors by interacting with them through the surface receptors. The precise role of the immune complexes is not well studied as the development of humoral response is considered favorable in some cancers and detrimental in others. Hence, we hypothesize that these immune complexes may promote or suppress targeted immunotherapeutic interventions such as dendritic cell (DC) based therapies. By studying the effects of these immune complexes upon DCs, predicting the outcome of treatment, and subsequently improving the efficacy of these targeted interventions may become possible. In our study, 5ml of blood samples were obtained from cervical cancer patients (n=6) for isolating ICs after an informed consent was obtained and Polyethylene glycol (PEG) precipitation. The precipitated ICs were then used to prime the PBMC-derived immature dendritic cells of the patients (n=3) at various concentrations (100ug/ml, 50ug/ml, and 25ug/ml) and evaluated for their phenotypic stability and functional efficacy. Phenotypic characterization of IC-primed dendritic cells through flow cytometry showed increased expression of HLA-DR and the co-stimulatory marker CD86 at 100ug/ml when compared to 50ug/ml and 25ug/ml. However, HLA-G, CTLA4 (CD152), and other inhibitory markers were also higher at 100ug/ml when compared to priming at 50ug/ml. Hence, IC-primed dendritic cells can be explored as an efficient priming strategy for cell-based therapy when compared to single TAA-primed dendritic cells.

Abstract no.: 2
Category: Clinical
Title: Prevalence And Serological Evaluation Of Direct Antiglobulin Test in Paediatric Patient Population: Experience From A Tertiary Health Care Hospital Centre in North India.
Author/s: Dr. Faisal Ashraf
Senior Resident SKIMS, MCH, J&K, India
Dr Meena Sidhu Hod GMC
Aims and Objectives: To find the prevelance, causes and serological evaluation of DAT positive patients.
Methods: A hospital-based cross-sectional observational study was conducted over a period of one year with effect from November 2020 to October 2021. The study population comprised of pediatric patients which met our inclusion and exclusion criteria. These patients were tested for Polyspecific DAT by Column Agglutination Technique (CAT) and later subjected to Monospecific DAT using same technique.
Results and Discussion: Out of all 542 hospitalized pediatric patients included in the study, 31(5.72%) patients had a positive polyspecific DAT, of which 18(58.06%) were males and 13(41.94%) were females. Of the total 31 polyspecific DAT positive cases 08(25.81%) cases showed 1+ weak reaction, 15(48.39%) cases showed 2+ weak Reactions, 6(19.35%) cases showed 3+ strong reaction and 2(6.45%) cases showed 4+ strong reaction. After performing Mono specific DAT test on positive Polyspecific DAT cases, it was noticed that C3b/d component showed reactivity in 38.71% followed by both IgG, C3b/d in 25.80% cases.Majority of cases 13(41.94%) were found to have infection followed by sepsis 07(22.58%) cases.In DAT positive results, majority of cases were diagnosed to have infection 13(41.94%),followed by sepsis 07(22.58%). Out of 13 cases of infection, pneumonia comprised majority of cases followed by gastro enteritis. Positive statistical co relation of DAT positivity with anemia was observed ($p < 0.05$*).
Conclusion: The prevalence of DAT positivity in our study was 5.72% with C3b/d component being most common cause of DAT. Infection and Sepsis were commonly found to show DAT positive results with C3b/d only. Sr LDH and sr indirect bilirubin was found to be raised among most of DAT positive cases but only sr indirect bilirubin was statistically significant (p< 0.05*). Although severe anemia was in majority of cases but reticulocyte count was found to be decreased in two-thirds of DAT positive cases. Although 5.72% of the patients were DAT positive, it was not commonly associated with hemolysis

Abstract no.: 3
Category: Manufacturing

Title: Fixed Bed Bioreactor-Based Production of Adeno-Associated Viral Vector "From Bench to Pilot Scale"

Author/s: Dr. Ruchita Selot
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Aim: To establish AAV vector production process in a fixed bed bioreactor that can serve as a scalable protocol for GMP grade vector production platform.

Objective: To optimize AAV vector production process for critical parameters like cell number, transfection, harvesting methods, etc.

Methods: All bioreactor runs were performed in Cytiva® iCellis Nano bioreactor (1.06 m 2) (schema provided below). The Hek293T cells were seeded at 30,000 cells/cm 2 following aseptic conditions and expanded to reach 1.7-2x10 6 cells/c.s. before transfection with packaging plasmids [pRep2-Cap9, pHelper, and pAAV-ITR.EGFP] and PEIPro® (Polyplus). Culture media was harvested at 72 hrs and 120 hrs post-transfection followed by final lysis from carrier strips. Vector titration and quality checks were carried out following standard methodologies.

Results and Discussion: Multiple bioreactor runs were conducted to determine optimal cell numbers for seeding, growth, and in situ transfection. Fig. 1B illustrates uniform adhesion of Hek293T cells to PET carrier strip of bioreactor up to 120 hours post-seeding, despite changes in media flow rates. Consistent cell growth and effective PEI-mediated transfection (Fig. 1B, middle panel) were observed, facilitating AAV vector packaging. To obtain higher vector yields, pDNA content relative to cell numbers was adjusted which resulted in significant increase (8-fold increase; crude yield 4.92 x10 14 vgc vs. 5.66 x10 13 vgc) (Fig. 2A), while maintaining vector quality. Post-transfection media glucose concentration was maintained at 25 mM, creating a nutrient-rich and stress-free environment for cells (Fig. 2B) which helped extend cycle duration before final harvest. The purified vector upon transduction in Hek293T cells yielded successful EGFP expression.

Conclusion: Our findings highlight the pivotal role of variables like cell seeding, DNA content per cell, and harvesting duration to enhance vector yields. This bioreactor-based vector production protocol can be adapted effectively for pilot-scale production processes (2.25mt2 and 4mt2 bioreactors).

Abstract no.: 4

Title: Improving the Efficacy of Dendritic Cell Based Vaccines by Targeting IDO-1 Using Repurposed Drugs

Author/s: Ms. Anusha Jayachander
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Cancer Institute (WIA)

Indoleamine 2, 3 dioxygenase (IDO-1) is an enzyme that catabolizes the first and rate limiting step of tryptophan metabolism along the L-Kynurenine pathway. It is increased within dendritic cells, triple negative breast cancer cells and other cells in the tumour microenvironment. Therefore, we hypothesize that targeting IDO activity may enhance the functional efficacy of the Dendritic Cells which may otherwise suppress responses in patients who receive dendritic cell vaccine therapy. Three repurposed drug candidates- named as drug Candidates 1,2,3 upon docking and simulation studies, were identified to target IDO-1. THP-1, a monocytic cell line was used to generate Dendritic cells as nearly 70% of THP-1 cells constitutively express IDO-1 and these were treated with the repurposed drug candidates (in their IC50 concentration) and their impact on dendritic cell viability as well as reduction in IDO1 activity were assessed. Drug treated IDCs were monitored for three days and analysed for their viability and IDO1 expression Kynurenine formation was also monitored in the culture medium using HPLC. The drug treated IDCs derived from THP-1 cells were lysed and analysed for their inhibitory effects on IDO-1 via tryptophan depletion and kynurenine synthesis. These cells were also checked for alteration of IDO-1 protein expression using Flow cytometric analysis(n=5) cells The production of N-Formyl Kyneurinine was shown to be lower in candidate 2 treated cells and the IDO-1 activity in the drug treated lysates ranged from 4-16mU/mg. All the drug treated cells were found to be more than 95% (±3) viable. The drug treated cell supernatants also were found to have reduced K/T ratio (n=5) after 72h. However,the cells did not show much alterations in IDO-1 expression which ranged from 19%to 39%. The studies are ongoing for generating matured DCs primed with TNBC lysate along with the drug candidates and assessing their efficacy.

Abstract no.: 5

Title: Unveiling the LncRNA Landscape post-CAR-T therapy in Multiple Myeloma

Author/s: Ms. Subhiksha Sundaram, M.Sc
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Aim: To investigate the variations in the expression levels of long non-coding RNA (lncRNA) in samples from patients with multiple myeloma (MM) undergoing CAR-T therapy.

METHODOLOGY: Single-cell RNA sequencing data from five peripheral blood mononuclear cells (PBMC) samples of patients with MM were obtained at the time of leukapheresis and 28 days post-CAR-T therapy. The data was retrieved from the Sequence Read Archive (SRA). The acquired data underwent processing, including quality checks. Subsequently, cell clustering was conducted, and differentially expressed genes with a significance threshold of p-value< 0.05 in individual cells were identified.

RESULTS: Following the single-cell clustering analysis of PBMC cells, distinct clusters were recognized, encompassing T-cells, monocytes, and natural killer cells. Additional identified clusters consisted of pre-B cells, erythroblasts, platelets, macrophages, neutrophils, and dendritic cells.

Conducting individual differential expression analyses for the three clusters under pre-and post-CAR-T infusion conditions unveiled 2825 genes for the T-cell cluster, 7638 for NK cells, and 7615 for monocytes, all of which surpassed the specified cut-off value. The identification of non-coding RNA linked to these genes was conducted, and a compilation of commonly upregulated genes has been provided below:

HCP5, TTN-AS1, CCDC18-AS1, HCG17, HCG18, MIR29B2CHG, LINC02384, NUTM2B-AS1, FTX, TRG-AS1, STX18-AS1, JPX, LINC00339, DLEU2, DIRC3, LINC01588, DAXX, SAP30L-AS1, NEAT1, MBNL1-AS1, SNHG14, LINC00649, LINC00847, NUTM2A-AS1, SPATA13, LINC02328, LINC00623, HMGA1P4, PCBP1-AS1, CKMT2-AS1, XIST, LINC00861, LINC01138, TPT1-AS1.

DISCUSSION AND CONCLUSION: The 34 non-coding RNAs that exhibit consistent overexpression in T cells, NK cells, and monocytes predominantly consist of long non-coding RNAs (lncRNAs). Upon conducting pathway analysis, it was observed that all the upregulated genes are linked to apoptosis, suggesting a potential association with T-cell death. Among them, NEAT1 has been linked to the regulation of cell proliferation in various cancer types, including MM. Silencing NEAT1 has proved to disrupt its normal regulatory functions, potentially causing dysregulation in cell cycle control and a decrease in cell proliferation. The sustained upregulation of NEAT1 in T-cells and other immune cells post-CAR-T therapy suggests its potential oncogenic role. Targeting NEAT1 and other epigenetic factors is imperative to enhance the efficiency of CAR-T cell therapy. While the association of other lncRNAs with different cancer types is established, their specific role in MM remains to be fully elucidated.

Abstract no.: 6

Title: Setting-Up A CAR Garage: Preparation for an Optimal Leukapheresis Collection.

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Rizwan Javed, Consultant Apheresis & Cellular therapy, Jeevan Kumar J, Arijit Nag, Amrita Gope, Dibakar Podder, Debranjani Chattopadhyay, Shouriyo Ghosh, Deepak Mishra, Sanjay Bhattacharya, Reena Nair, Mammen Chandy

Background: The first step in chimeric antigen receptor (CAR) T-cell therapy is leukapheresis for T-cell collection. It is imperative to establish collection procedures that ensures optimal quality of the starting material for successful manufacturing and treatment (Qayed et al, 2022) for both adult and pediatric patients who are being planned to receive immune effector cell (IEC) therapies either commercially or through clinical trails. Transplant centres with a functional peripheral stem cell collection unit are required to take additional measures for optimal leukapheresis collection for CAR-T production

Aim: To develop institutional workflow for patients undergoing leukapheresis collection for CAR-T cell production

Methods: A literature search was initiated in PubMed and Google databases for International standards and leukapheresis guidelines for optimal CAR-T manufacturing published in the last five years. Reference lists were cross-checked for relevant citations, and more searches were undertaken till the desired information was obtained. The information was discussed with all stake-holders over several meetings to develop a strategy our facility. The multiple steps involved in the adequate collection of source material was identified and the overall development of the workflow was guided by the Principal Investigator/ Physician, Apheresis physician, nursing leadership, laboratory In- charge, Co-ordinator, quality specialist and hospital administration.

Results and Discussion: Responsibilities were delegated to individuals based on their training. Consents, Pre-leukapheresis screening and product release SOPs were drafted. Risk assessments and additional considerations (as detailed below) including regulatory and accreditation compliance were systematically documented. Several critical steps for successful leukapheresis of CAR-T products were identified and a work-flow was prepared including the following:

- Regulatory & Accreditation requirements
- Patient evaluation and vascular access
- T-cell Collection
- Product Quality assessment, Labelling and release
- Patient on-boarding
- Pre-collection Assessment
- Post-collection care

Conclusion: An established leukapheresis collection algorithm improves collection success and prevents over collection. Based on current International guidelines and second edition of FACT standards for Immune Effector Cells, our facility was able to successfully prepare the workflow, SOPs and conduct risk-assessments for an optimal leukapheresis for CAR-T production.

Abstract no.: 7

Title: Dendritic Cell-based Immunotherapy for Stage IIIB Cervical Cancer Patients: Immune Monitoring of a Phase II Clinical Trial

Author/s: Dr. Abirami Seetharaman
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Indian Institute of Technology Madras

Cervical cancer is the fourth most common cause of cancer among women worldwide, with 9.1% of mortality rate. The primary end point of this Phase II study was to assess the immune response in patients towards dendritic cell vaccine as an adjuvant with chemoradiotherapy, a standard line of treatment for stage IIIB cervical cancer.

Out of 182 patients screened for the study 54 patients with cervical cancer stage IIIB were recruited after obtaining an Institutional Ethics committee-approved audio-video informed consent as mandated by the DCGI. Eighteen patients each were randomized to receive either placebo, autologous tumor lysate primed (TLPDC), or recombinant human SPAG9 (rhSPAG9) primed DC (rSPDC), all in addition to the standard of care- concurrent chemo-radiotherapy. The peripheral blood samples collected before and after treatment was used for performing the immune monitoring assays.

Post-treatment immunological assessments allowed the characterization of immune responses directed at specific antigens. The development of post treatment immune response was confirmed by quantifying antigen-specific IFN gamma release by effector T cells using IFN-gamma ELISpot assay which showed 61% of TLPDCs and 77% of rSPDCs stimulated samples had a significantly higher IFN production with two-fold increase in proliferation of CD4+, CD8+, and CD56+ cells determined using the CFSE-based cell proliferation assay.

Secreted cytokine profile of the supernatants was also analyzed, which supported the development of Th1 and Th2 response by both TLPDC and rSPDC.

Our data describes not only systemic immune response after DC-based immunotherapy but also evaluated antigen-specific response T-cell responses in vitro, after treatment in patients with advanced cervical cancer. The results reflect the development of systemic cell-mediated immunity in patients, which indicates the potential of these immune monitoring assays as a therapeutic predictive marker for patients undergoing immunotherapy.

Abstract no.: 8

Title: Production & Comparison of AAV Serotypes: Purification Methods, And In Vivo Administration Routes For Enhanced Gene Therapy Efficacy

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Aims and Objectives: To optimize the production process and compare recombinant adeno-associated virus (rAAV) AAV6, AAV8, AAV9 carrying the alkaline phosphatase (AP) transgene. The investigation involved evaluating purification methods (CsCl2-based ultracentrifugation and chromatography) and assessing transduction efficiency in vitro and in vivo. Additionally, we aimed to identify the optimal route of administration (RoA) and serotype for efficient transgene delivery in the mouse brain.

Methods: The AP transgene was incorporated into AAV6, AAV8, and AAV9 via triple transfection in HEK 293T cells. Post-transfection, cell lysates underwent CsCl 2 -based ultracentrifugation, and supernatant was purified using a multi-serotype affinity column. Purified vector were quantified revealing % yields, genomic titers (slot blot & qPCR), quality checked for purity (silver staining and western blot), and in vitro transduction efficiency (AP assay). Capsid occupancy ratio was determined using transmission electron microscopy (TEM). AAV vectors were administered via intracerebroventricular (ICV), intrathecal (IT), and intravenous (IV) routes, and AP expression was assessed.

Results and Discussion: Affinity purification demonstrated superior recovery rates (>95%) and slightly increased transduction efficiency compared to CsCl 2 ultracentrifugation. Silver staining and western blot analysis confirmed the higher quality of affinity-purified AAV fractions. TEM revealed diverse capsid subclasses, with a higher occupancy ratio in chromatography fractions. ICV administration exhibited superior gene delivery to mice brains compared to IT and IV routes.

Conclusion: This study underscores the superior efficacy of affinity purification over CsCl 2 -based ultracentrifugation in AAV production. ICV administration proved more effective for gene delivery to mouse brains than IT and IV routes. These findings emphasize the significance of strategic purification method selection in manufacturing and RoA for optimal gene therapy outcomes.

Abstract no.: 9

Title: Genetic engineering of autologous donor cells for exosomal cargo modulation and immunotherapy.

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Katha Sanyal, Anushka Banerjee, and Abhijit Gitendranath Banerjee*

Introduction: In the fields of immunotherapy and regenerative medicine, genetic engineering has become a potent tool. The innovative approach of engineering donor cells for exosomal cargo modification, aims to enhance their therapeutic potential for immunotherapy applications.Donor cells for instance MSCs, immune cells, dendritic cells etc. selected for their compatibility and regenerative properties are genetically engineered to manipulate the composition of exosomes they release. Different genetic manipulation methods are used to customize the exosomal cargo for particular microenvironment immunomodulatory effects, such as plasmids, viral vectors, RNA interference, and CRISPR/Cas9.

The engineered donor cells exhibit precise control over the content of exosomes, influencing the types and amounts of proteins, nucleic acids, and other bioactive molecules. This allows for the customization of exosomes to carry payloads that optimize immunotherapeutic outcomes. Pre- and post loading mechanisms of exosomes have been described for different cargoes. The tailored exosomes play a pivotal role in immune system modulation, fostering enhanced communication between immune cells and promoting targeted responses against diseases such as cancer, autoimmune disorders, and infectious pathogens. This approach holds promise for improving the efficacy and safety of immunotherapies.

Aims and Objectives: This review aims to define genetic engineering approaches in donor cells for exosomal modulation, thus presenting exciting possibilities, addressing challenges such as off-target effects, ethical concerns, and regulatory frameworks. In order to advance this technology, maintaining a balance between safety and customization is still essential.

Methods: Accordingly, literature was reviewed pertaining to the last decade using keywords defined below and boolean operators in various databases.

Results and Discussion: The integration of advanced genetic engineering techniques and a deeper understanding of exosomal biology opens avenues for further research. Future studies might focus on refining the precision through cargo modification, elucidating the long-term effects, and expanding the repertoire of therapeutic applications.

Conclusion: Genetic engineering of donor cells for modulation of cargo represents a cutting-edge approach in immunotherapy, offering a customizable platform for tailoring exosomes. This strategy holds great potential for revolutionizing the landscape of potential therapeutic interventions, providing new avenues for precision medicine and improved patient outcomes.

Keywords: Exosomes; gene therapy; Immunotherapy; bionano delivery; Cell therapy

Abstract no.: 10

Title: The Centre of Excellence in Cellular Immunotherapy – Fast-Tracking Cellular Therapies to the Clinic

Author/s: Dr. Jessica Li
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Peter MacCallum Cancer Centre

The Centre of Excellence in Cellular Immunotherapy (CoE CIT), located at the Peter MacCallum Cancer Centre in Melbourne, Australia, was established as a Cellular Immunotherapy IP Accelerator Platform: to collaboratively identify, develop and deliver globally competitive and commercially viable breakthroughs in CAR-T and other cellular immunotherapies for the treatment of cancer. Co-funded by the Australian Federal Government, the Peter Mac Foundation and Peter Mac, in partnership with the co-located GMP contract manufacturing organisation Cell Therapies Pty. Ltd. (CTPL), the CoE CIT partners with Australian academic researchers and small biotech companies to fast-track innovative discovery research into cell-based therapy products delivered to the clinic in the form of pilot proof-of-concept clinical trials. The CoE CIT provides a fully funded Development Program that includes preclinical safety testing, method of manufacture optimisation, tech transfer to CTPL for GMP manufacturing, and running of a Phase I clinical trial. Supported by the broader translational, clinical and manufacturing ecosystem within the Parkville precinct, the CoE CIT Development Program provides a unique platform that delivers translational capabilities for novel cellular immunotherapies, with the aim of achieving commercial outcomes to advance Australian-generated IP. In this talk, we will introduce the Centre's capabilities, goals and outline the Development Program.

Abstract no.: 11

Title: Microbial Contaminations and Management in CAR-T Cells

Author/s: Hemant K. Gautam
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Aims and Objective: Microbes pose a substantial concern in advanced therapeutic CAR-T cell production and delivery. T cells are modified to express chimeric antigen receptors (CARs) to target and kill cancer cells in CAR-T cell treatment. Thus, these novel medicines have faced many challenges. New quick approaches that satisfy high throughput performance while offering equivalent outcomes may alleviate these issues. From T cell collection to patient infusion, rigorous control is needed to avoid microbial contamination.

Methodology: Molecular diagnostics quickly identify infections and their genetic variations for subclassification, diagnosis, prognosis, and therapeutic response monitoring. 16S rRNA sequencing, metagenomics, whole genome sequencing, Nextgen sequencing, Nanopore sequencing, polymerase chain reaction, MALDI-TOF MS, and LAMP discover culturable and unculturable pathogens or single co-infections within hours. Epidemiological research uses nucleic acid testing to identify bacteria and determine taxonomic relatedness. CAR T cell therapy using third-generation nanopore sequencing, MALDI TOF, and flow cytometry may detect harmful bacteria quickly.

Result and Discussion: Microbial biosafety assessments are critical in defining the safety profile of CAR- T cells treatments prior to clinical translation. A thorough understanding of target pathogens, as well as their rapid detection methods, ensures the safety and efficacy of these novel immunotherapies during the following clinical development stages. Advanced techniques are utilized for the goal of detecting, screening, quantifying, and identifying. Examples encompass sterility testing to detect, screening to identify specified microorganisms, calculation of the total aerobic microbial count for enumeration, and analysis to identify specific microbes

Conclusion: Regulatory organizations provide stringent criteria for detecting microbial contamination in CAR-T cell therapies, and these guidelines should be critical to ensuring the therapy's safety and efficacy. Contamination can have catastrophic consequences, including as infections in patients undergoing treatment.

Abstract no.: 12

Title: Hematopoietic stem cell graft manipulation (minimal) by cell therapy labs supporting hematopoietic stem cell transplants in India

Author/s: Dr. Satyam Arora
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Aims and objectives: To study the heterogenicity in hematopoietic stem cell graft manipulation (minimal) in cell therapy labs supporting hematopoietic stem cell transplants in India.

Methods: An epidemiological descriptive cross-sectional survey (55 questions) of the centre providing HSCT in India was planned to capture the reporting centre's demographic details as well as variations in their policies and practices of HSCT graft minimal manipulation (plasma reduction, RBC depletion and cryopreservation).

Results and discussion: Sixty-four centres responded to the survey (63/102; response rate: 62.7%) and majorly from the Northern part of India (27 out of 63; 42.1%). The majority of reporting centres reported performing >50 HSCTs annually (n=24; 39%) and 92% (58 out of 63) of the reporting centres performed stem cell collections from a paediatric donor/ patient (age < 18 years). Minimal product manipulations were performed by 56 of 63 centres (more than one type of manipulation): cryopreservation (n=45), plasma reduction (n=42), and RBC depletion (n=28). Cryopreservation was primarily done by blood centres (60%, 27 of 45) with DMSO being the primary constituent with the most common concentration of 5-10% (62%; 28/45 centres) being used. “Dump freezing” (using -80°C deep freezer) was the most common mode of freezing used (60%; 27/45 centres). “7AAD flow cytometry” based viability assessment was most commonly done (66%; 30/45 centres) post cryopreservation. Thawing of the product was done majorly at the bedside (66%; 30/45 centres) using majorly a “wet type” thawer (80%; 36/45 centres) and washing of DMSO was done by a few centres (15.5%; 7/45 centres). “Plasma reduction” and “RBC depletion” was primarily done for ABO incompatibility at blood centres.

Conclusion: This survey identifies the lack of standardization and uniformity in the minimal manipulation of HSC at labs with centres supporting HSCT in India. This work also highlights the need for more studies and country-specific recommendations to establish best practices.

Abstract no.: 13

Title: Path To Lab Accreditation And Improvements

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Introduction: Medical laboratories are the key partners in patient safety. Laboratory results influence 70% of medical diagnoses. Quality of laboratory service is the major factor which directly affects the quality of health care. Accreditation is a process by which an authorative body gives formal recognition that an organisation is competent to carry out specific tasks.

Aim and Objective:

- The clinical laboratory as a whole has to provide the best patient care promoting excellence.
- So to enhance credibility and competency of our testing services we choose the path of Accrediting our lab.

Materials and Methods: We have started the process of accreditation in 2007 and its effect on our lab till date 2023. We have referred and applied International Standard ISO 15189, based upon ISO 17025 and ISO 9001 standards, which provides requirements for competence and quality of medical laboratories. Dividing the NCs in following categories 1. Pre Examination. 2 Examination 3. Post Examination. 4. Management.

Results: ISO 15189 requirements consist of two parts, one is management requirements and the other is technical requirements. Basis on that we have got 23 NCs in the first year 2008, followed by improvements in coming years. In 2011 we got 7 NCs, 2012 7NCs , in 2013 we brought down to 4NCs ,on further improvement in 2015 & 2017 we got only 1NC and in 2019 we received Zero NC. After covid, assessment took place in 2022 were we got 2 NC.

Conclusion: The study conclude that Laboratory Quality Management System (LQMS) in medical testing laboratories explicate the need for understanding current standard requirements of quality system implementation and maintenance to improve the quality of service of the laboratories and facilitate accreditation which in turn will improve management system and their technical competence.

Abstract no.: 14

Title: Laboratory sample rejections analysis in the pre-analytical stage at an oncology centre

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Introduction: Clinical laboratories play a crucial role in the diagnosis and management of patients. These are some of the key indicators of errors that can help & identify potential improvements in patient safety during pre-analytical phase in clinical laboratories. Errors in clinical laboratories have a great impact on safety and care of patients. The pre-analytical phase is responsible for about 70% of errors.

Aims and Objectives:

- To evaluate the reasons for sample rejection and effect of corrective actions on the same.
- Quality indicators in clinical laboratory provide a useful tool for continuous improvement of laboratory services.

Materials and Methods: A retrospective, intervention and prospective analysis of the samples rejected from the total samples received in our laboratories, during a period from Jan 2020 to Dec 2022 was undertaken.

Results and Observations: Out of 216631 samples received during Jan 2020 to Dec 2022 , 318 samples (0.15 %) were rejected. The most common reasons for rejection is clotted blood samples (57.14 %) followed by improperly labelled samples (14.28%), haemolysed samples(11.42%), insufficient sample volume (8.57%), Samples without requisition(5.71%) & Samples in expired vacutainers (2.85%)

After continuous intervention drop in sample rejection was observed from 163 samples to 41 samples (i.e from 51.2% to 12.8 %) from total rejection of 318 samples.

Conclusion: This study has shown that the most frequent causes of pre-analytical errors are clotted sample, improperly labeled samples, haemolysed samples & samples with insufficient volume. Significant drop in sample rejections post-interventions shows that analysis of rejections and corrective actions help improve patient safety and care.

Abstract no.: 15

Title: Design and operation of a good manufacturing practices (GMP) laboratory in India

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Introduction: Cellular therapy is a rapidly evolving field worldwide. Both academic and commercial centers are planning to build their own facility to manufacture cell and gene therapy products (CGT). These centers are increasingly working to design and build clinical laboratories capable of performing cellular engineering and vector production using current good manufacturing practices (cGMPs). However, GMP facilities and CGT products are tightly controlled by regulators and numerous country specific approvals and licensure are required for it functioning. Hence, manufacturing of CGT products has become increasingly complicated and costly. It is imperative to have knowledge of current country specific regulations and design GMP appropriate for the type of manipulation

Aim and Objective: To design a good manufacturing practices (GMP) laboratory in compliance with current guidelines and regulations

Methods: A literature search was initiated in PubMed and Google databases for International standards, Government regulations and current guidelines for setting up a GMP laboratory. Reference lists were cross checked for relevant citations, and more searches were undertaken till the desired information was obtained. The information was discussed with all stake-holders over several meetings to develop a GMP facility design with country-specific regulatory requirements. In India, SCHEDULE M of Drugs and cosmetics Act elaborates on the Good manufacturing practices and requirements of premises, Plant and equipment for pharmaceutical products. In USA, Food and Drug Administration (FDA) provides guidance.

Results: In compliance to regulatory requirements, a GMP design and process flow was developed (see Firgure-1) below. The different areas have been colored shared and process flow depicted in red arrows. The gowning space provides space for the storage of gowning materials. Gowning area has a changing room and a clear division between “clean” and “dirty” sides of the room as indicated by the positioning of a bench between the two areas. The gowning room leads into the main central corridor along which are located the manufacturing suites, the clean storage room, and the cold storage facility

Abstract no.: 16

Title: Tailoring CAR NK Cells For Enhanced Anti-Tumor Activity And Persistence Against Haematological Malignancies

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Aims and Objectives: This study aims to optimize CAR-NK cell constructs for B-cell leukaemia and lymphoma by tailoring dual specificity domains (CD19/CD22 or CD19/CD20), incorporating an NK-specific co-stimulatory element, and armoring with IL-15. The objective is to achieve increased cytotoxicity and enhanced in-vivo persistence compared to conventional CAR-NK cells.

Methodology: Approximately 30 CAR designs, including mono and bi-specific CARs with various co-stimulatory domains, were developed. Synthetic sequences were inserted into a lentiviral vector using overlapping PCR and/or Gibson Assembly, followed by validation through sequencing. Constructs were introduced into NK-92 cells via electroporation, and CAR expression was assessed using flow cytometry. In vitro, evaluations against Raji-Luc-mCherry target cells revealed significant anti-tumor activity, especially with optimized combinations of co-stimulatory domains.

Results and Discussion: Phase I of the study involved designing and cloning 30 CAR-NK constructs, with the top 10 selected based on high mRNA expression in HEK-293 cells. In phase II, electroporation of selected CARs into NK-92MI cells demonstrated potent cytotoxicity against Raji-Luc-mCherry cells, particularly with NKG2D transmembrane and DAP10-2B4, 41BB-2B4, and 4B-DAP10 co-stimulatory domains, achieving an ~80% tumor elimination with a fold change of 20 compared to control.

Conclusion: This study identifies promising CAR-NK constructs for B-cell malignancies, offering an alternative to CAR-T cell therapy. The incorporation of specific co-stimulatory domains, particularly NKG2D transmembrane with DAP10-2B4, 41BB-2B4, and 4B-DAP10, demonstrated remarkable potency in tumor elimination. Future research will delve into comprehensive in vitro and in vivo studies to understand the mechanisms underlying the superior anti-tumor activity of these CAR-NK constructs compared to conventional designs. In conclusion, our study provides a proof of concept, laying the groundwork for highly effective and potentially personalized CAR-NK therapies

Abstract no.: 17

Engineering Off-the-Shelf Gamma Delta CAR T cells for the Treatment of Acute Myeloid Leukemia

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Chimeric antigen receptor T cell therapy (CART) therapy has shown remarkable success in the treatment of B cell acute lymphoblastic leukemias (B-ALL) and lymphomas. However, CART therapies for acute myeloid leukemia (AML), where 5-year survival rates are significantly lower than for B-ALL, are only in their infancy. CD33-CART have potent activity against AML in preclinical models and a first-in-child/first-in-human phase 1/2 CD33-CART clinical trial for AML is ongoing in the Pediatric Oncology Branch of the National Cancer Institute (NCT03971799). Nonetheless, published outcomes suggest a modest efficacy of approximately 50% (Shahzad et al., Front Immunol 2023), highlighting the critical need to develop new strategies to improve CART accessibility and a more robust anti-AML response. We hypothesized that off-the-shelf gamma delta (γδ) CD33 CART cells could potentially overcome current challenges for the treatment of AML. γδ lineage T cells are unconventional lymphocytes whose functions are not restricted to MHC-mediated antigen presentation; they are primed for immediate responses, including tumor killing. Furthermore, allogeneic γδ T cells have the potential to induce robust anti-tumor cytotoxicity without causing graft versus host disease (GVHD).

Here, we generated γδ CAR T cells from healthy donor elutriated lymphocytes by activation with zoledronic acid and IL-2 for 7-14 days. Within 9 days post stimulation, the vast majority of lymphocytes were Vδ2+ and 30-40% were successfully transduced with a lentiviral CD33 CAR construct harboring the 4-1BB costimulatory domain. Importantly, and unlike conventional alpha beta (ab) T lymphocytes, >98% of these γδ CD33CAR T cells expressed IFN under basal conditions. This characteristic likely accounted for the efficient in vitro killing of AML cell lines by untransduced γδ T lymphocytes under conditions of high effector/target (E/T) ratios. While untransduced γδ T cells did not exhibit cytotoxicity following repeat AML stimulations, γδ CD33CAR T lymphocytes exhibited proficient in vitro cytotoxicity, with killing rates that were more rapid than those initiated by ab CD33 CART. These characteristics were associated with a prolonged metabolic activity of γδ T cells; γδ CD33 CART expressed high levels of the GLUT1 glucose transporter for >14 days post activation whereas GLUT1 levels on ab CD33 CART returned to resting within 10 days. Most notably, γδ CD33CAR T lymphocytes achieved high in vivo cytotoxicity, assessed using bioluminescent AML cell line xenografts in humanized NSG mice. Together, these data highlight the feasibility of generating allogeneic gd CD33CART with a strong anti-AML cytotoxic response.

UPCOMING SACT EVENT

4th SACT EVENT

organised by
CAR-T & Cell Therapy Centre (CTCTC), MUMBAI

3 days Hands-on

Workshop

on GMP Cell Therpay Manufacturing & QA/QC

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No of delagtes :30

5th SACT Event

An Asia - Pacific Cell Therapy Conference & Hands-on Workshop Series

organised by

CAR-T & CELL THERAPY CENTRE, ACTREC, TATA MEMORIAL CENTRE, MUMBAI

March 2025

NAVI MUMBAI, INDIA

SACT-2025

Series of Advancements in Cell Therapy


3rd SACT EVENT
SACT-2024
Series On Advancements in Cell Therapy
Accelerate the Path to New Cell Therapies in India