Investigation of specific microRNA signatures of the tumor microenvironment as a predictive biomarker for immunotherapy

UNIVERSITÄTS KLINIKUM FREIBURG

Molekulare Onkologie

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Who are we?

Laboratory of Molecular Oncology

P.I.: Prof. Dr. Thalia Erbes

- head of the Breast Cancer Center at the Clinic for Gynecology at the Freiburg University Medical Center
- Gynecological oncologist
- Gynecological oncologist surgeon
- Translational research:

molecular biological development and validation of (liquid) biomarkers in diagnostics and therapy monitoring of breast and gynecological carcinomas, tumor-relevant drug analysis in vitro

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Investigation of specific **microRNA signatures** of the tumor microenvironment as a predictive biomarker for immunotherapy

Project Idea:

Development of a robust noninvasive biomarker for the prediction of a therapy response to immunotherapeutics

- miRNA signature
- Urine – blood – tissue
- Basket design
- Retrospectively and prospectively possible by evaluating patient data on outcome

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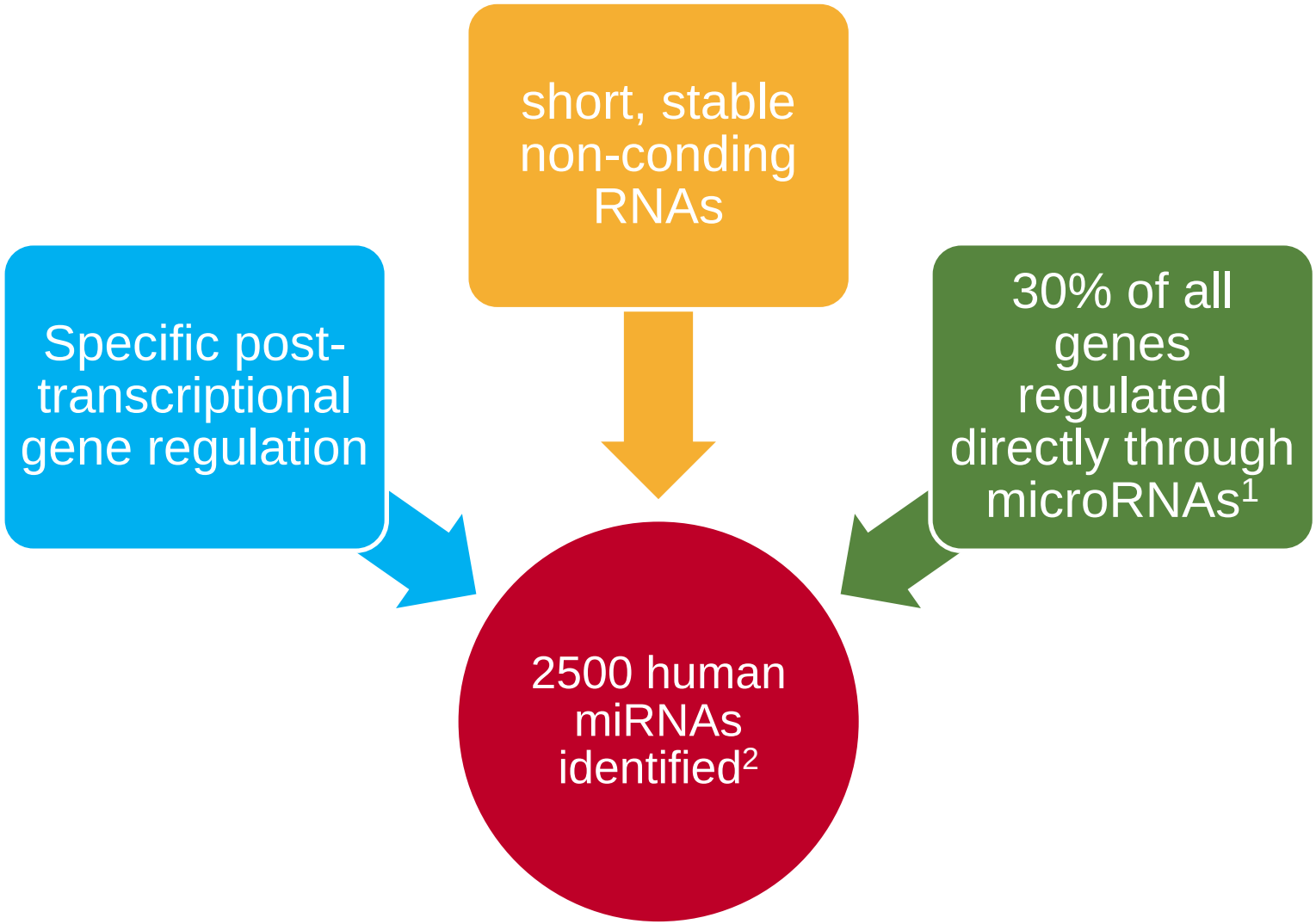
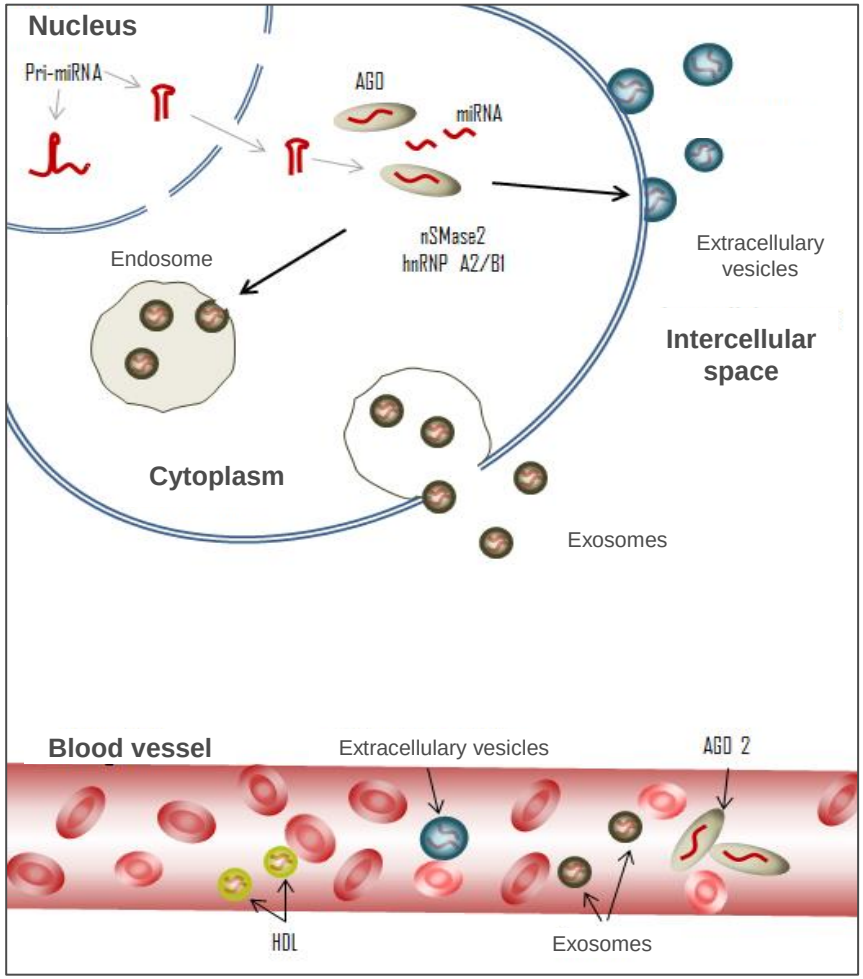
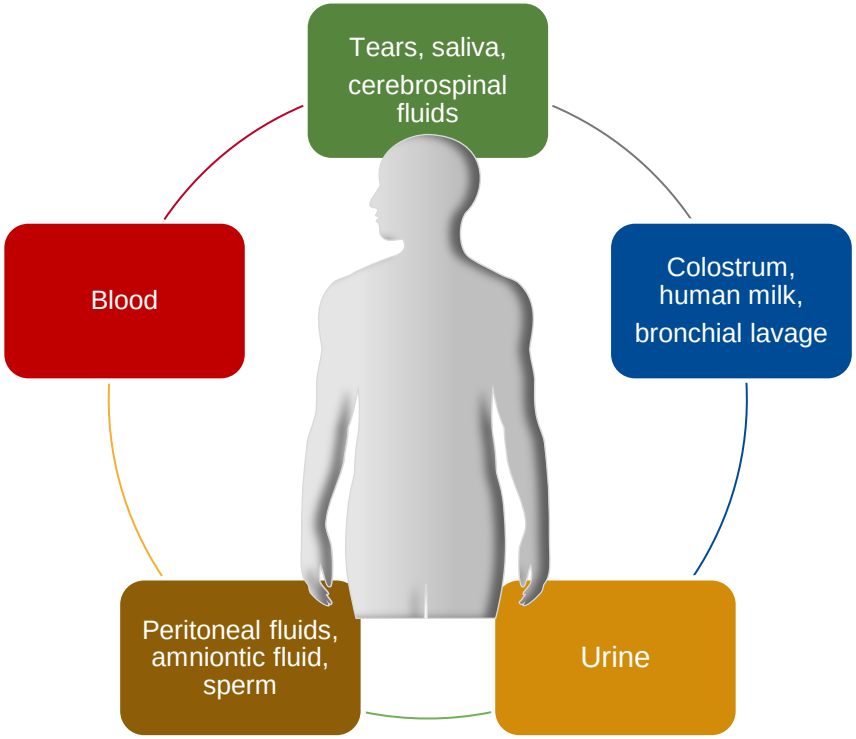
microRNAs



1. Lewis BP et al. Cell. 2005;120(1):15–20.
2. www.mirbase.org

Circulating microRNAs in body fluids





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2015: Proof of Principle Study

Erbes *et al. BMC Cancer* (2015) 15:193
DOI 10.1186/s12885-015-1190-4

BMC Cancer

RESEARCH ARTICLE Open Access

Feasibility of urinary microRNA detection in breast cancer patients and its potential as an innovative non-invasive biomarker

Breast cancer detection via sets of 4 urinary miRNAs
sensitivity: 83,3%, specifity: 87,8% Spezifität 87,8%

Patent: EP No. 3070178 (B1),
US Pat. No. 10246749 (B2))

2020: Enhanced Screening Study

Molecular Diagnosis & Therapy (2020) 24:215–232
https://doi.org/10.1007/s40291-020-00453-y

ORIGINAL RESEARCH ARTICLE

Check for updates

Urinary Exosomal MicroRNAs as Potential Non-invasive Biomarkers in Breast Cancer Detection

Marc Hirschfeld[1,2,3] · Gerta Rücker[2,4] · Daniela Weiß[1,2] · Kai Berner[1,2] · Andrea Ritter[1,2] · Markus Jäger[1,2] · Thalia Erbes[1,2]

Breast cancer detection via sets of 4 urinary miRNAs
sensitivity: 98,6%, specifity: 100%

Patend pending EP1910989

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BMBF Grant VIP+:
Clinical validation study and automation

Bundesministerium für Bildung und Forschung

Sehr geehrte Damen und Herren,

1. Höhe der Zuwendung/Finanzierungsform und -art/Zweckbindung/Bewilligungszeitraum/ Zahlungsplan

im Auftrag und aus Mitteln des Bundesministeriums für Bildung und Forschung bewilligen wir Ihnen als beliehener Projektträger als Projektförderung eine nicht rückzahlbare Zuwendung bis zu 1.299.965,00 € höchstens jedoch in Höhe der zuwendungsfähigen Ausgaben (Vollfinanzierung)

zuzüglich einer Projektpauschale in Höhe von 259.993,00 € (20,00 % der für die zuwendungsfähigen Ausgaben gewährten Zuwendung des BMBF).

Damit beträgt die Zuwendung inklusive Projektpauschale

1.559.958,00 €

(in Buchstaben: Eins-fünf-fünf-neun-neun-fünf-acht Euro).

Runtime: 3 Years, start Q4 2020

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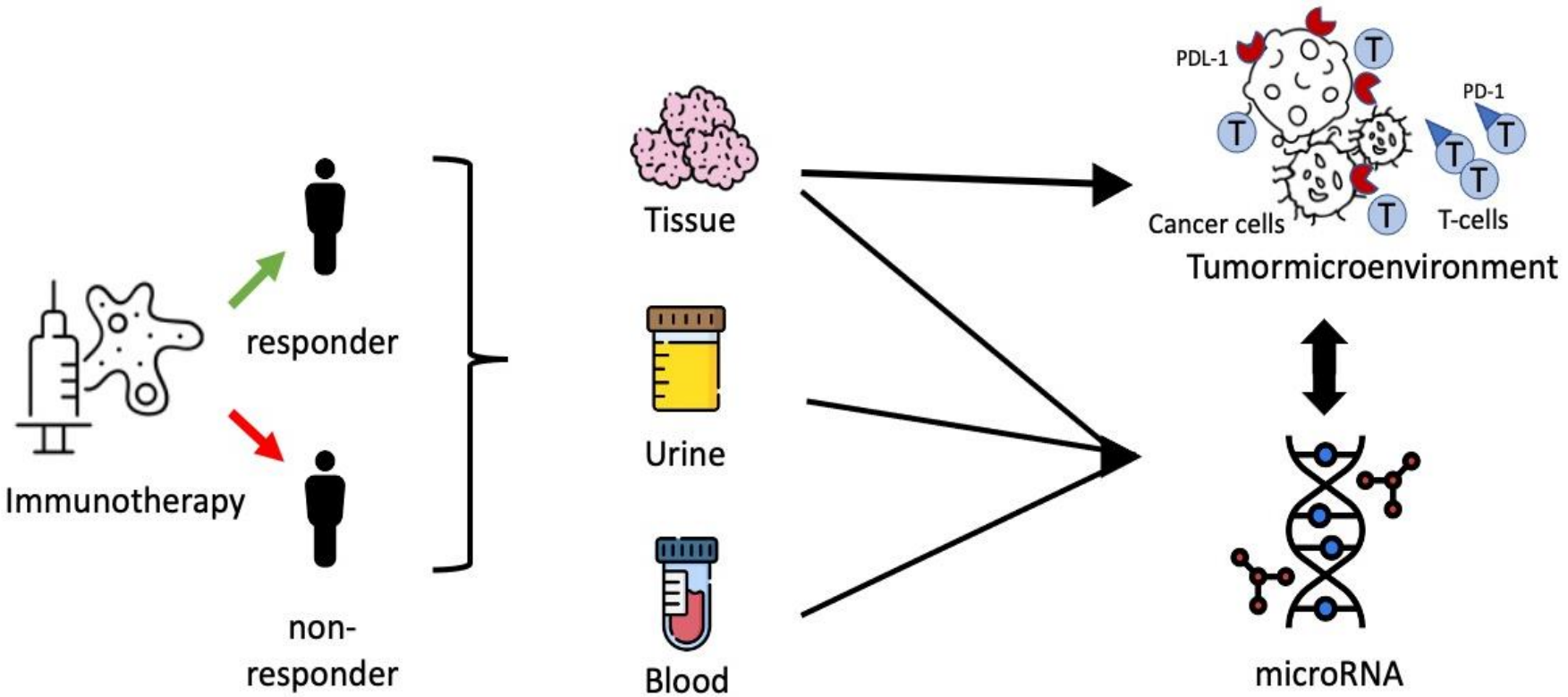
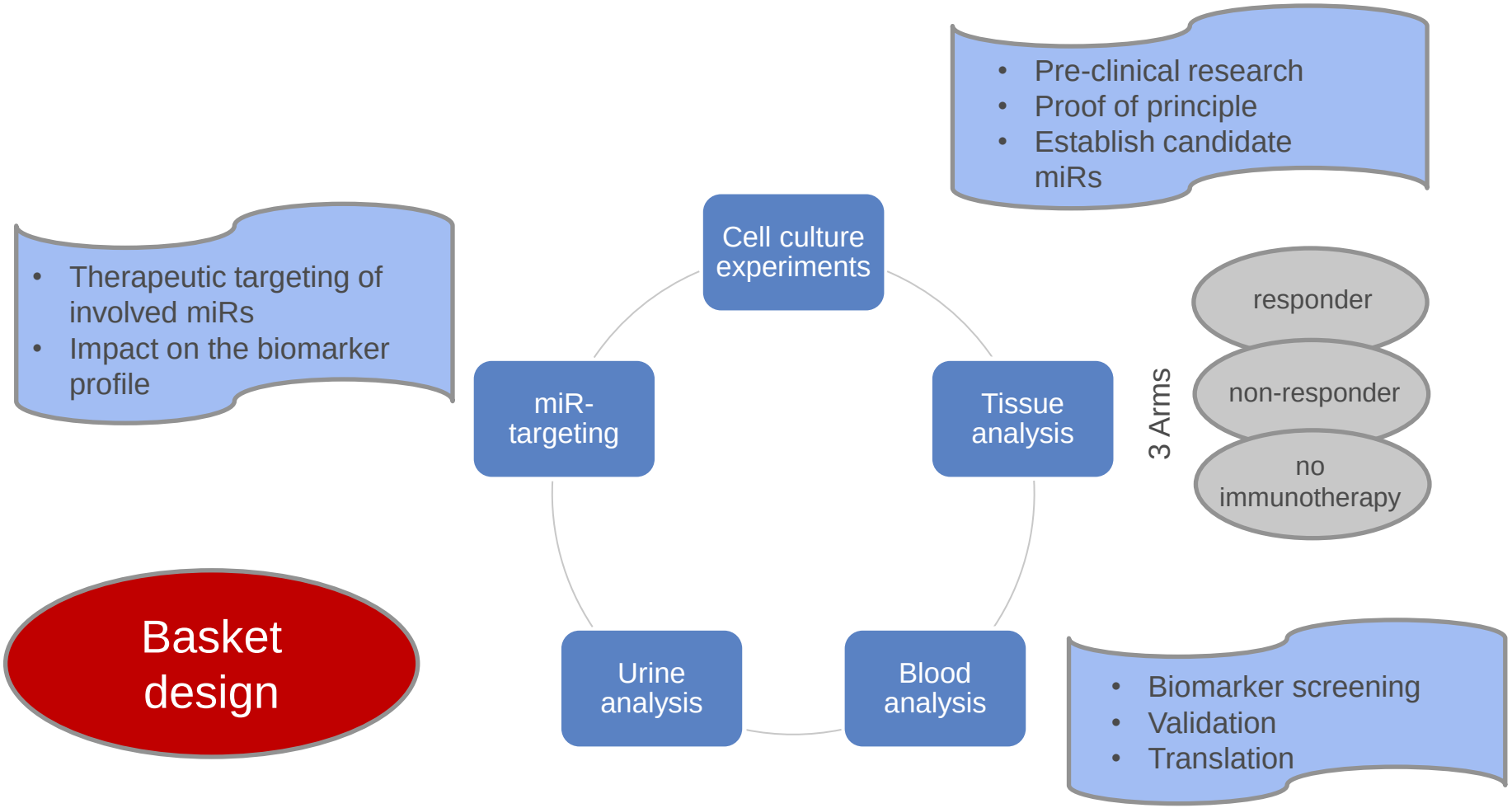
Project Idea: Investigation of specific **microRNA signatures** of the tumor microenvironment as a predictive biomarker for immunotherapy



Project Overview – 5 pillars approach



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What are we looking for in partnering?

First steps:

Identification of TME-components and miRNA signature, establish candidate miRNAs (qPCR, immune histochemical staining), molecular pathways

- **Cell culture experiments, preclinical research**
- **Tissue**: molecular tumor conference – already available with immunooncology panel (PDL-1, PD-1, TILs)

Further steps:

Sample collection in cancer patients with/without immunotherapy and analysis of tumormicroenvironment / miRNA signature

- Urine
- **Blood**

Final steps:

- **Translational approach, validation, therapy prediction**
- **Therapeutic targeting**

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