

# Trans-PALLAS

## Overview of PALLAS translational research program and call for research proposals



# PALLAS status and timelines

- **End of Treatment Phase: July 2020**
  - **Final Endpoint Analysis (469 iDFS):**
    - date of awareness 20-Nov-2020 (EC/SC data review in May 2021)
    - **presentation of data planned at SABCS 2021 and manuscript in preparation**
- Protocol related research is followed by additional **Research Project Proposals** for surplus samples and associated data in the PALLAS network.
- **First Call for proposal submission open from 15 Sept 2021 – 15 Jan 2022**



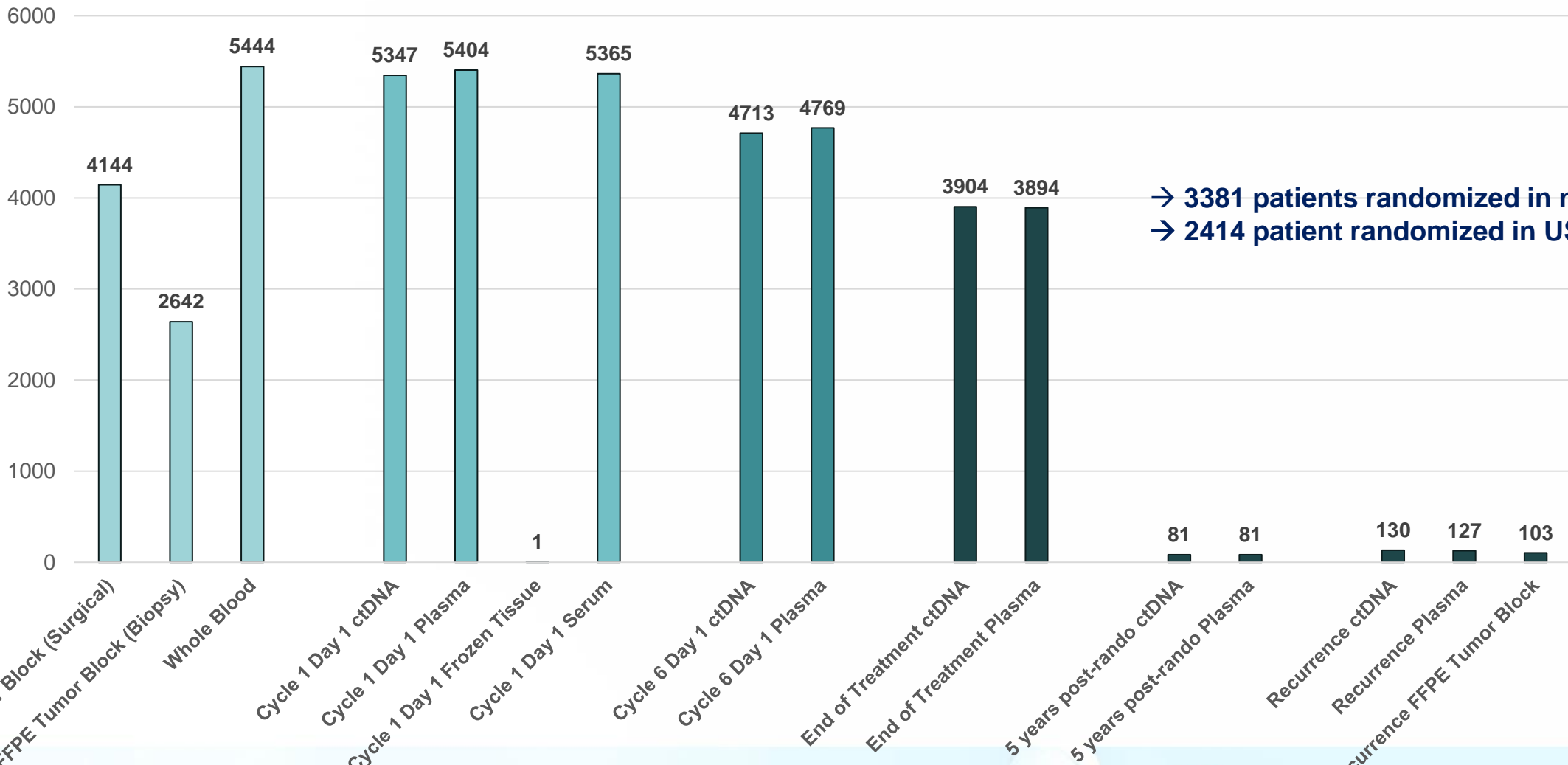
# Timepoints of Sample Collection per PALLAS Study Protocol (Schedule of Assessments)

Type of Sample	Collection Timepoint(s)	Amount of Sample collected per timepoint (per Protocol)
FFPE Tumor Block (Core Biopsy and/or surgical specimen)	<ul style="list-style-type: none"> <li>• Baseline (Randomization)</li> <li>• Timepoint of recurrence*</li> </ul>	1 specimen/ sample
Whole Blood	<ul style="list-style-type: none"> <li>• Pre-treatment or Cycle 2/day 1</li> </ul>	8,5 ml
Serum	<ul style="list-style-type: none"> <li>• Pre-treatment</li> </ul>	from 9 ml blood
Circulating cfDNA	<ul style="list-style-type: none"> <li>• Pre-treatment</li> <li>• Cycle 6/day 1</li> <li>• End of treatment and/or timepoint of recurrence*</li> <li>• 5, 7 &amp; 10 years post-randomization</li> </ul>	from 2 x 10 ml blood (approx. 5 ml plasma)
Plasma	<ul style="list-style-type: none"> <li>• Pre-treatment</li> <li>• Cycle 6/day 1</li> <li>• End of treatment and/or timepoint of recurrence*</li> <li>• 5, 7 &amp; 10 years post-randomization</li> </ul>	from 9 ml blood

*\*only for patients with recurrence*



# Available trans-PALLAS Samples (combined in US and non-US Biobanks)



→ 3381 patients randomized in non-US  
 → 2414 patient randomized in US



# Ongoing & planned pre-defined trans-PALLAS Projects

## Pre-defined Trans-PALLAS Projects

- RNA Sequencing of baseline tumor samples of all PALLAS patients - *ongoing*
- HTG Sequencing of selected PALLAS patients – *ongoing*
- ctDNA analysis of selected PALLAS patients – *in planning*
- GWAS and WES approaches addressing protocol defined objectives – *in planning*
- Validation of biomarker assays and pre-defined signatures - *in planning*

### *Additional envisioned approaches:*

- *Analysis of bulk RNA-Seq profiles*
- *Analysis of immune infiltration and immunogenicity*
- *Digital pathology approaches*



# Ongoing & planned pre-defined Clinical Science Research Projects

## Pre-defined Clinical Science Research Projects

- PRO analysis – *ongoing*
- Analysis of chemotherapy induced amenorrhea - *planned*
- Discontinuation and adherence analyses - *ongoing*
- BMI analysis - *ongoing*

### *Additional planned protocol-specified analyses:*

- *Analysis of COVID outcomes - ongoing*
- *Analysis of post-recurrence treatments - planned*
- *Overall survival analysis - planned*
- *Stage IIa subgroup analysis - planned*



# Research Project Proposals (RPP) – addressing objectives not defined in the study Protocol

- **Research Project Proposals (RPP)**
  - Include study data and samples as well as data generated from samples (e.g. sequencing data)
  - Globally harmonized review process and approval by EC and SC committees
  - Workflow and review defined in „PALLAS Policy for Access to Study Data or Surplus Samples for Research Projects not related to the Protocol”
- **2 types of proposals can be submitted:**
  - Clinical Science Research Projects (CSRP): Data only
  - Trans-PALLAS Translational Research Projects (TRP): Data and surplus samples or data generated from those samples
- **Summary of Review and approval process:**



# Call for Research Project Proposals

**First RPP Call open for submission from 15-Sep-2021 until 15-Jan-2022**

→ Review of all submitted proposals and feedback to investigators in **Q1 2022**

RPP submission is **open to all PALLAS Investigators**

**Please address proposal submissions and inquiries to**

**[pallas.research@abcsbg.at](mailto:pallas.research@abcsbg.at)**

Dr. Jana Link (ABCSG) coordinates proposal administration, submission status, progress of RPPs, and reports to the study sponsors

**Submission form** and further information can be downloaded from the **PALLAS Study Portal** → **<https://www.pallasportal.com/Investigator/News/StudyUpdates>**

(access only for assigned non-US PALLAS Site Staff)

**or requested via email.**

