

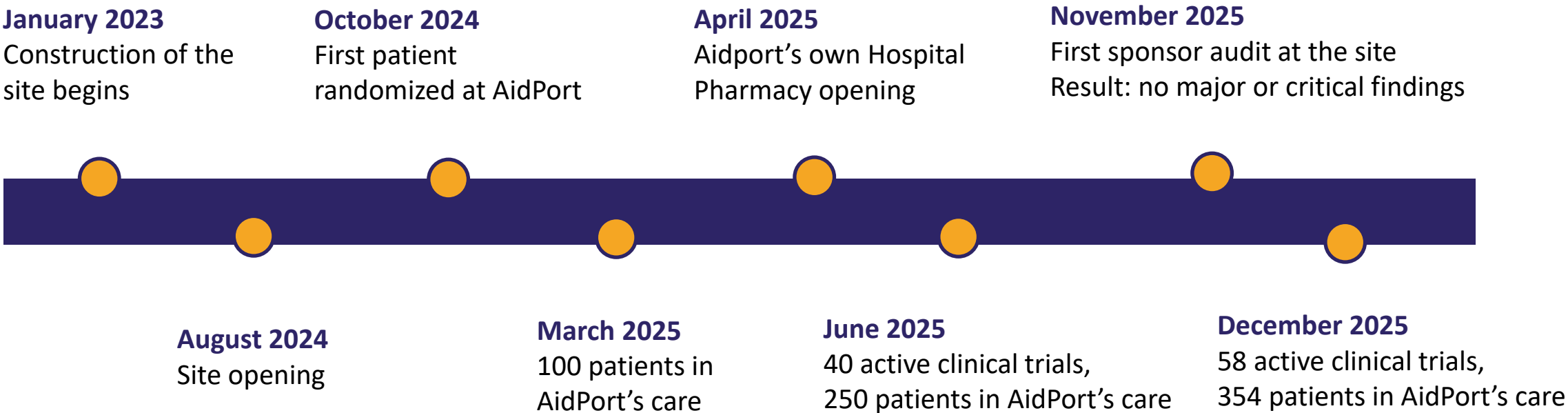


AidPort
Clinical Trials Hospital



AIDPORT TIMELINE

AidPort Site Development Timeline





1,300 square meters of space **DEDICATED** to clinical trials:

- ONCO-HEMATOLOGY WARD (**10** INFUSION STATIONS)
- HOSPITAL PHARMACY
- OUTPATIENT AMBULATORY (**10** MEDICAL OFFICES)
- DXA SCANNER
- SPONSOR / CRO AREA (**SPACE FOR 15** CRA'S)
- STUDY COORDINATORS AREA (**DEDICATED SPACE FOR 20** SC'S)

LOCALIZATION: SKORZEWO NEAR POZNAN, WEST POLAND



AIDPORT IS READY TO START (construction from 2022 to 2024)



PATIENT SERVICE AREA



STUDY COORDINATORS AND SPONSOR / CRO AREA



HOSPITAL AREA



ONCOLOGY - THERAPEUTIC AREAS

- GENITOURINARY CANCER (kidney, urothelial, prostate, testicular)
- BREAST CANCER
- GYNECOLOGIC CANCER (cervical, endometrium, vaginal)
- GASTROINTESTINAL CANCER (gastric, colorectal)
- HEAD AND NECK CANCER
- MELANOMA
- THORACIC CANCER (lung cancer)
- HEMATOLOGY – ONCOLOGY (leukemia, lymphomas)

HEMATOLOGY - THERAPEUTIC AREAS

- **LYMPHOMAS (NHL-B, NHL-T, HL)**
- **CHRONIC LYMPHOCYTIC LEUKEMIA (CLL)**
- **ACUTE MYELOID LEUKEMIA (non-transplant group)**
- **MYELOPROLIFERATIVE DISEASES (PV, ET, CML, MF)**
- **RARE DISEASES (ITP, PNH)**

WOMEN'S HEALTH - THERAPEUTIC AREAS

- **ENDOMETRIOSIS**
- **UTERINE FIBROIDS**
- **HOT FLASHES (menopausal or secondary to another treatment)**
- **OSTEOPOROSIS**
- **CONTRACEPTION**
- **INFECTION PROPHYLAXIS (HPV)**

CARDIOLOGY - THERAPEUTIC AREAS

- ♡ **PREVENTIVE CARDIOLOGY**
- ♡ **HEART FAILURE**
- ♡ **ISCHEMIC HEART DISEASE**
- ♡ **VALVULAR HEART DISEASE**
- ♡ **SYSTEMIC HYPERTENSION**
- ♡ **HEART RHYTHM DISTURBANCES**
- ♡ **DYSLIPIDEMIA**
- ♡ **DIABETOLOGY**
- ♡ **OBESITY AND METABOLIC DISORDERS**

PULMONOLOGY - THERAPEUTIC AREAS

- **INTERSTITIAL LUNG DISEASE**
- **ASTHMA**
- **CHRONIC OBSTRUCTIVE PULMONARY DISEASE**
- **RSV / COVID / FLU**

NEUROLOGY - THERAPEUTIC AREAS

- **PARKINSON'S DISEASE**
- **EPILEPSY**
- **ALZHEIMER'S DISEASE**
- **RRMS**
- **MIGRAINE**
- **MULTIPLE SCLEROSIS**
- **MYASTHENIA GRAVIS**

RHEUMATOLOGY - THERAPEUTIC AREAS

- **SJOGREN'S SYNDROME**
- **RHEUMATOID ARTHRITIS**
- **LUPUS**
- **PSORIATIC ARTHRITIS AND DISEASE ACCOMPANYING
INTESTINAL DISORDERS**



ONCOLOGY TEAM:

Piotr Tomczak MD, PhD

Renata Szoszkiewicz MD, PhD

HEMATOLOGY TEAM:

Michał Kwiatek MD, PhD

Lukasz Pruchniewski MD, PhD

Maciej Kazmierczak MD, PhD

WOMEN'S HEALTH TEAM:

Prof. Krzysztof Szymanowski MD, PhD

CARDIOLOGY TEAM:

Michał Lewandowski MD, PhD

Anna Komosa MD, PhD

Magdalena Łanocha MD, PhD

PULMONOLOGY TEAM:

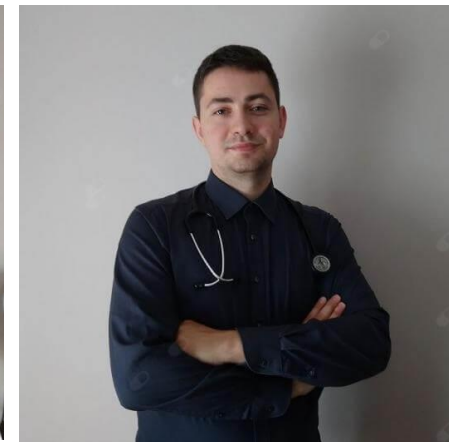
Marcin Bednarek MD, PhD

NEUROLOGY TEAM:

Karolina Piasecka – Stryczyńska MD, PhD

RHEUMATOLOGY TEAM:

Magdalena Szyszko MD, PhD



ONE 'TRIO' HEMATO-TEAM SINCE 2014



ONCO - EXPERIENCE



INDICATION	PHASE	RECRUITMENT PERIOD	RANDOMIZATION
MCRC 1ST LINE	1	2021-2022	4
KIDNEY CANCER, MELANOMA	1	2020-2021	32
MELANOMA	3	2022 – ongoing	5
TNBC	2	2018 – 2019	9
BREAST CANCER HR+/HER2-	3	2021 – 2022	4
UROTHELIAL CANCER	2	2020 – 2021	12
UROTHELIAL CANCER: NEOADJUVAT TREATMENT	3	2023 – ongoing	5
SOLID TUMORS AFTER STANDARD: BASKET STUDY	1	2022 – ongoing	6
MCRC WITH PI3K MUTATION	1	2020 – 2022	3
PROSTATE CANCER	1	2021 – 2022	6
TNBC	3	2022 – 2022	5



INDICATION	PHASE	RECRUITMENT PERIOD	RANDOMIZATION
AML	2	2017-2019	26
ITP.	2	2017-2018	16
ITP.	3	2021-2021	10
MF after JAK-I	3	2021 - currently	6
CLL	3	2019-2020	49
CLL	3	2022-2022	14
1 L CLL / RR CLL	2	2022 - 2023	18
R/R DLBCL	3	2021 - currently	14
INDOLENT NHL-B	1	2021-2022	9
NHL-B	1	2021-2022	5
NHL-B	1	2021-2022	17
1 L CLL / RR CLL	3	2022 - currently	12
ITP.	2	2022-2022	9
R/R FL	3	2022 - currently	6
R/R FL	2	2020-2021	9
R/R NHL-B	1	2023 - currently	4
PNH	3	2021-2021	2
PNH	3	2021-2021	2
1 L DLBCL	2	2023 - 2023	4
R/R NHL-B	1	2022-2022	9
R/R MCL	3	2022 - currently	4

WOMEN'S HEALTH - EXPERIENCE



INDICATION	PHASE	RECRUITMENT PERIOD	RANDOMIZATION
FIBROIDS	3	2018-2019	10
ENDOMETRIOSIS	3	2019-2020	34
ENDOMETRIOSIS	2	2021-2022	17
OSTEOPOROSIS	3	2020	56
OSTEOPOROSIS	3	2022	26
HOT FLASHES	3	2020-2021	104
HOT FLASHES	3	2021-2021	12
HOT FLASHES	2	2021-2021	24
HOT FLASHES – ADJUVAT THERAPY OF BREAST CANCER	3	2022 – ONGOING	9



CARDIOLOGY - EXPERIENCE

INDICATION	PHASE	RECRUITMENT PERIOD	RANDOMIZATION
PULMONARY ARTERIAL HYPERTENSION	2	2024 - 2025	1
PULMONARY ARTERIAL HYPERTENSION (PAH)	2B/3	2023-2024	1
ATHEROSCLEROTIC CARDIOVASCULAR DISEASE	3	2022 – ongoing	14
CHRONIC HEART FAILURE	1	2023 – 2024	3
HEART FAILURE	2	2022 - 2024	3
HEART FAILURE AFTER MYOCARDIAL INFARCTION	2	2022 – 2024	10
ATRIAL FIBRILLATION	3	2019-2021	18
ACUTE CORONARY SYNDROME	3	2018-2021	12
DYSLIPIDEMIA	3	2016-2018	17
ATRIAL FIBRILLATION	3	2015-2017	18
ISCHEMIC HEART DISEASE	3	2016 – 2018	14



CARDIOLOGY - EXPERIENCE

INDICATION	PHASE	RECRUITMENT PERIOD	RANDOMIZATION
ACUTE CORONARY SYNDROMES	3	2013 - 2016	22
ISCHEMIC HEART DISEASE	3	2012 - 2014	6
ISCHEMIC HEART DISEASE	1	2019 – 2022	8
ACUTE CORONARY SYNDROME	2	2019 – 2021	14
ACUTE CORONARY SYNDROME	3	2017 - 2020	35
ISCHEMIC HEART DISEASE	2	2018 - 2019	8
HEART FAILURE	2	2018 – 2020	12
HEART FAILURE	2	2016 -2018	4
ISCHEMIC HEART DISEASE	2	2017 - 2019	8
ISCHEMIC HEART DISEASE	3	2018 - 2020	34
ISCHEMIC HEART DISEASE	3	2016 - 2020	8
DYSLIPIDEMIA	3	2017-2021	28
ACUTE CORONARY SYNDROME	3	2018 - 2020	10
ISCHEMIC HEART DISEASE	3	2019 - 2021	8



CARDIOLOGY - EXPERIENCE

INDICATION	PHASE	RECRUITMENT PERIOD	RANDOMIZATION
ISCHEMIC HEART DISEASE	3	2018 - 2020	12
ACUTE CORONARY SYNDROME	3	2018 - 2021	72
DYSLIPIDEMIA	2	2012 – 2016	12
HEART FAILURE	3	2013 - 2015	4
HEART FAILURE	3	2014 - 2018	36
BIO DYSLIPIDEMIA	1	2016 - 2019	68



EARLY PHASES - EXPERIENCE

INDICATION	PHASE	RECRUITMENT PERIOD	RANDOMIZATION
RHEUMATOLOGY: DISCOID LUPUS ERYTHEMATOSUS, SUBACUTE CUTANEOUS LUPUS ERYTHEMATOSUS OR SYSTEMIC LUPUS ERYTHEMATOSUS	1B	2021 – ongoing	1
GASTROENTEROLOGY: PULMONARY CIRRHOSIS OF THE LIVER	2B	2024 - 2025	1
DERMATOLOGY: MODERATE TO SEVERE ATOPIC DERMATITIS	2B	2024 – ongoing	1 (SF)
RHEUMATOLOGY: SYSTEMIC LUPUS ERYTHEMATOSUS	FIRST IN HUMAN	2024 - ongoing	
RHEUMATOLOGY: SYSTEMIC LUPUS ERYTHEMATOSUS	OPEN LABEL	2021 - 2023	1



NEUROLOGY - EXPERIENCE

INDICATION	PHASE	RECRUITMENT PERIOD	RANDOMIZATION
CHRONIC MIGRAINE – CM-MOH	4	2019 - 2022	c. 60 – TOP RECRUITER IN THE WORLD
RELAPSING MS - MS200527_0082 - <u>NATIONAL</u> <u>COORDINATOR</u>	3	2020 - 2024	c. 60 – TOP RECRUITER IN THE WORLD
PPMS - GN41791	3	2021 – ONGOING	9
RELAPSING MS - GN42272	3	2022 – ONGOING	30
RR MULTIPLE SCLEROSIS - WA40404 - <u>EASTERN</u> <u>EUROPE COORDINATOR</u>	3	2022 – ONGOING	6
RELAPSING MS - CLOU64C12301	3	2022 – ONGOING	41
MULTIPLE SCLEROSIS - BP42230	1	2023 – ONGOING	7
MYASTHENIA GRAVIS - VIB0551.P3.S1	3	2023 – ONGOING	3
RELAPSING MS - CTP53	1/3	2024 – ONGOING	34



RHEUMATOLOGY - EXPERIENCE

INDICATION	PHASE	RECRUITMENT PERIOD	RANDOMIZATION
SJOGREN'S SYNDROME - EUDRACT: 2021-005911-30	2	2023	5
SJOGREN'S SYNDROME - EUCT: 2023-503915-14-00	2	2023	4
SJOGREN'S SYNDROME NCT06747949	2	2023 - ONGOING	3
SJOGREN'S SYNDROME EUCT: 2024-516609-22-00	2	2025 - ONGOING	3
SJOGREN'S SYNDROME NCT06104124	2	2025 – ONGOING	3
SJOGREN'S SYNDROME NCT06312020	2	2024 – ONGOING	3
SJOGREN'S SYNDROME 417-201-00042	2	2025	1
RHEUMATOID ARTHRITIS EUCT: 2023-506664-14-00	3	2024 - 2025	4
PSORIATIC ARTHRITIS AND DISEASES ACCOMPANYING INTESTINAL DISORDERS EUCT: 2024-513111-27-00	3	2025	9

100 % ELECTRONIC HEALTH RECORD

- FULL **ELECTRONIC** SOURCE DOCUMENTATION IN VALIDATED SYSTEM **OPTIMED NXT**
- DIRECT ACCESS WITH **READ ONLY MODE** FOR CRA MONITORS, AUDITORS, INSPECTORS
- **AUDIT TRIAL** OF ANY ACTIONS THAT CREATES, MODIFIES OR DELETES
- ELECTRONIC SIGNATURE
- READY FOR **REMOTE MONITORING**

TREATMENT PROCESS DOCUMENTED IN EMR

1) Documentation regarding ordering laboratory tests and taking blood to determine parameters

Zlecenie

Typ zlecenia	Laboratorium	Pilne	Tak
Data wystawienia	2024-11-18 08:15	Data Planowana	2024-11-18
Jednostka zlecająca	Poradnia Hematologiczna	Jednostka realizująca	Punkt pobrań materiałów do badań
Status	Zrealizowane	Opis	Odebrano wyniki
Data anulowania	-	Osoba anulująca	-

Usługa	Status	Opis	Data pobrania	Osoba pobierająca	Kod próbki
Morfologia krwi (pełna)	Zrealizowane ⓘ		2024-11-18 09:07	WARKOCZ ARKADIUSZ	3718154941
Rozmaz krwi (manualnie)	Zrealizowane ⓘ		2024-11-18 09:07	WARKOCZ ARKADIUSZ	3718154941
Sód	Zrealizowane ⓘ		2024-11-18 09:07	WARKOCZ ARKADIUSZ	3718154941
Potas	Zrealizowane ⓘ		2024-11-18 09:07	WARKOCZ ARKADIUSZ	3718154941
Kreatynina	Zrealizowane ⓘ		2024-11-18 09:07	WARKOCZ ARKADIUSZ	3718154941
Bilirubina całkowita	Zrealizowane ⓘ		2024-11-18 09:07	WARKOCZ ARKADIUSZ	3718154941
Bilirubina związana (bezpośrednia)	Zrealizowane ⓘ		2024-11-18 09:07	WARKOCZ ARKADIUSZ	3718154941
AST	Zrealizowane ⓘ		2024-11-18 09:07	WARKOCZ ARKADIUSZ	3718154941
ALT	Zrealizowane ⓘ		2024-11-18 09:07	WARKOCZ ARKADIUSZ	3718154941
Retikulocyty - analiza parametrów metodą automatyczną	Zrealizowane ⓘ		2024-11-18 09:07	WARKOCZ ARKADIUSZ	3718154941
Beta-HCG	Zrealizowane ⓘ		2024-11-18 09:07	WARKOCZ ARKADIUSZ	3718154941

TREATMENT PROCESS DOCUMENTED IN EMR

2) Documentation of the results "flowing down" to the center and evaluation by the investigator

Historia wizytWizytaWynikiPodsumowanieKarta lekówZałączniki

Wszystkie wyniki

Istnieją wyniki do rozliczenia

Wyniki do rozliczenia

Zestawienie wyników laboratoryjnych

Od

Do

Filtr usług

Bilirubina związana (bezpośrednia) \$

2024-11-19 07:22

Bilirubina związana [0 - 0,3]

0.32 [mg/dl] H

ALT \$

2024-11-18 18:01

ALT [0 - 55]

9 [U/l]

AST \$

2024-11-18 18:01

AST [5 - 34]

14 [U/l]

Beta-HCG \$

2024-11-18 17:28

beta-HCG [-]

< 2,30 [mIU/ml]

Kreatynina \$

2024-11-18 17:28

Kreatynina [0,6 - 1,1]

0.84 [mg/dl]

eGFR [-]

>60 [ml/min/1,73m2]

Sód \$

2024-11-18 17:24

Sód [136 - 145]

140 [mmol/l]

Bilirubina całkowita \$

2024-11-18 17:24

Bilirubina całkowita [0,2 - 1,2]

0.64 [mg/dl]

Potas \$

2024-11-18 17:24

Osoba wypełniająca

KWIATEK MICHAŁ [2890349]

Wyniki poza normą + ocena i komentarz

Ocena wyników od 2024-11-18 16:15 do 2024-11-19 07:22

Bilirubina związana - NCS

Granulocyty pałeczkowate - NCS

Hematokryt - NCS

RDW-CV - NCS

Limfocyty - NCS

Dezaktywuj

Wydrukuj

Zamknij

Edytuj

KWIATEK MICHAŁ 2024-11-19 08:26

TREATMENT PROCESS DOCUMENTED IN EMR

3) Ordering the preparation of IMP by the hospital pharmacy / pharmacy department

Historia modyfikacji dokumentu

Dnia 2024-11-19 o godzinie 08:53:18 przez mkwiatek

Dnia 2024-11-19 o godzinie 08:38:07 przez mdraber

Dnia 2024-11-19 o godzinie 08:28:01 przez mkwiatek

Data i godzina wystawienia zlecenia	2024-11-19 08:25
Numer protokołu	GOLSEEK 2
Numer pacjenta	018700014
Nazwa wizyty	C1D1
Wzrost (cm)	176
Waga (kg)	78
Data pomiaru wagi	2024-11-19
BSA	1,97
Wzór użyty do wyliczenia BSA	<input type="radio"/> Mosteller <input checked="" type="radio"/> DuBois <input type="radio"/> Haycock
Planowana data podania leku	2024-11-19
Leki do przygotowania	Rituximab 739 mg (375mg/m2) Numery kitów lekowych: 213938 213939
Zatwierdzenie przez badacza	<input checked="" type="radio"/> Zatwierdzam
Imię i nazwisko zatwierdzającego	Michał Kwiatek

TREATMENT PROCESS DOCUMENTED IN EMR

4) Ordering drug administration (therapeutic decision)

Osoba modyfikująca	Status	Data planowana	Data realizacji	Dawka planowana	Dawka podana
KWIATEK MICHAŁ 2024-11-19 09:50	Potwierdzone	2024-11-19 09:50 KWIATEK MICHAŁ Profilaktyka TLS		500,00000 ml dożylnie,	
DUDA PAULINA 2024-11-19 14:12	Potwierdzone	2024-11-19 09:50 KWIATEK MICHAŁ Profilaktyka TLS		500,00000 ml dożylnie,	
DUDA PAULINA 2024-11-19 14:13	Zrealizowane	2024-11-19 09:50 KWIATEK MICHAŁ Profilaktyka TLS	2024-11-19 14:12 DUDA PAULINA	500,00000 ml dożylnie,	500,00000 ml

Podstawowe dane zlecenia

Data planowana

2024-11-1909:44

Jednostka zlecająca

Poradnia Hematologiczna

Osoba zlecająca

KWIATEK MICHAŁ [2890349]

Jednostka realizująca

Poradnia Hematologiczna

Apap noc x 50t. (tabl., 500mg + 25mg), Doustnie

doustnie

premedykacja przeciwgorączkowo

dec

pilne

Podawaj

Jednorazowo

W godzinach

09:44

Z dawką

mg

Stalą

Zmienną

09:44

Jednorazowo

1050

Demezón 4mg x 10 amp. (roztw. do wstrz., 4 mg/ml), Dostawowo, Domięśniowo, Dożylnie, Podskórníe

dożylnie

premedykacja - przeciwuczuleniowo

dec

pilne

Podawaj

Jednorazowo

W godzinach

09:44

Z dawką

mg

Stalą

Zmienną

09:44

Jednorazowo

8

TREATMENT PROCESS DOCUMENTED IN EMR

5) Drug administration card with all infusion parameters

+ ≡ ▾	2024-11-20, śr	2024-11-19, wt	2024-11-18, pn
Rituximab 500 mg (CA073-1022) + NATRIUM CHLORATUM 0,9% BAXTER 100 ml 739 mg / 500 ml <i>Pompa, podano 743.73 mg</i> <i>Czas podawania: 1 min</i> dożylnie		<i>Podano 743.73 mg</i> ... +8 14:00 272 ml/h 14:05 500 ml 14:06 0 ml/h	
Leki nieaktywne			
NATRIUM CHLORATUM 0,9% import 500 ml roztw. do inf., 9 mg/ml dożylnie		14:12 500 ml ⓘ ⓘ	
Demezon 4mg x 10 amp. roztw. do wstrz., 4 mg/ml dożylnie		09:58 8 mg ⓘ ⓘ	
Apap noc x 50t. tabl., 500mg + 25mg doustnie		09:58 1050 mg ⓘ ⓘ	
BMS986369 0.2 MG (CA073-1022) kaps., 0.2 mg doustnie		10:30 0.2 mg ⓘ ⓘ	
Milurit 300mg x 30t.		14:10 300 mg ⓘ ⓘ	

2024-11-19 14:12
DUDA PAULINA

2024-11-19 14:11
DUDA PAULINA

2024-11-19 14:01
DUDA PAULINA

2024-11-19 13:30
DUDA PAULINA

2024-11-19 13:05
DUDA PAULINA

2024-11-19 12:30
DUDA PAULINA

2024-11-19 12:00
DUDA PAULINA

2024-11-19 11:30
DUDA PAULINA

2024-11-19 11:03
DUDA PAULINA

	Ostatnia modyfikacja	Obowiązuje od	Przepływ	Bolus	Ustawiono
	DUDA PAULINA 2024-11-19 10:30	2024-11-19 10:30	34 ml/h		Tak
	DUDA PAULINA 2024-11-19 11:03	2024-11-19 11:00	68 ml/h		Tak
	DUDA PAULINA 2024-11-19 11:30	2024-11-19 11:30	102 ml/h		Tak
	DUDA PAULINA 2024-11-19 12:00	2024-11-19 12:00	136 ml/h		Tak
	DUDA PAULINA 2024-11-19 12:30	2024-11-19 12:30	170 ml/h		Tak
	DUDA PAULINA 2024-11-19 13:05	2024-11-19 13:00	204 ml/h		Tak
	DUDA PAULINA 2024-11-19 13:30	2024-11-19 13:30	238 ml/h		Tak
	DUDA PAULINA 2024-11-19 14:01	2024-11-19 14:00	272 ml/h		Tak
✎	DUDA PAULINA 2024-11-19 14:12	2024-11-19 14:08 -> 2024-11-19 14:06	0 ml/h		Tak

AIDPORT HOSPITAL PHARMACY

- **NEWLY COMMISSIONED FACILITY (MAY 2025) — DESIGNED TO MEET THE NEEDS OF MODERN CLINICAL TRIALS**
- **TWO CERTIFIED LAMINAR FLOW HOODS: ONE DEDICATED TO THE PREPARATION OF CYTOTOXIC (ONCOLOGY) DRUGS, ONE DEDICATED TO THE PREPARATION OF INVESTIGATIONAL MEDICINAL PRODUCTS (IMPS) AND OTHER CLINICAL TRIAL MEDICATIONS**
- **HIGHEST STANDARDS OF COMPLIANCE AND QUALITY**
- **FULL ALIGNMENT WITH CLINICAL TRIAL PROTOCOLS, ICH-GCP, AND APPLICABLE REGULATORY REQUIREMENTS**
- **STRINGENT QUALITY ASSURANCE AND DOCUMENTATION PROCEDURES: FULLY ELECTRONIC & INTEGRATED PROCESS, SEAMLESS INTEGRATION WITH ELECTRONIC MEDICAL RECORDS (EMR)**



QMS – TEMPERATURE (IP AND SAMPLES)

- CENTRAL TEMPERATURE RECORDING SYSTEM - OVER **30 MEASUREMENT POINTS** THROUGHOUT THE HOSPITAL
- NOTIFICATION SYSTEM - **SMS** TO THE DIRECTOR OF THE CENTER, THE PRINCIPAL INVESTIGATOR AND THE CHIEF PHARMACIST OF THE HOSPITAL
- REAL-TIME TEMPERATURE RECORDS, WITH **REMOTE ACCESS 24/7/365**
- BACKUP POWER SOURCE - A GENERATOR THAT ALLOWS THE HOSPITAL TO **MAINTAIN CONTINUOUS OPERATION** AFTER THE ELECTRICITY IS CUT OFF

✚ QMS – TEMPERATURE (IP AND SAMPLES)



20 TEMP-CONTROL DEVICES CONNECTED WITH ALARM SYSTEM



POWER BACK-UP (30 HOURS)



AIDPORT QMS

- WE WORK BASED ON OVER **50 PROCEDURES DESCRIBED IN THE SOP**, WHICH ARE VISIBLE FOR SPONSORS AND CRO
- WE HAVE AN INTERNAL TRAINING SYSTEM WITH DOCUMENTED TRAINING LOGS FOR **ALL TEAM MEMBERS**
- EXTENSIVE TEAM EXPERIENCE IN INTERNAL **AUDITS AND INSPECTIONS**
- A **DEDICATED QUALITY TEAM** BUILT BASED ON OPINION LEADERS IN EACH CLINICAL RESEARCH SECTOR

STANDARD OPERATING PROCEDURES (SOPs)

- THE CLINICAL RESEARCH SITE ADHERES TO DETAILED **STANDARD OPERATING PROCEDURES (SOPS)** TO ENSURE HIGH QUALITY, SAFETY, AND REGULATORY COMPLIANCE. THE SOPS ARE DIVIDED INTO THE FOLLOWING CATEGORIES:

1.PHARMACEUTICAL SOPS

2.MEDICAL SOPS

3.ORGANIZATIONAL SOPS

4.OPERATIONAL SOPS

5.EPIDEMIOLOGICAL SOPS

6.QUALITY SOPS



RECRUITMENT STRATEGY

- OWN **DATABASE** (OVER 2000 PATIENTS WITH HEMATOLOGICAL MALIGNANCIES)
- **REFFERALS** FROM MACRO-REGION OF WEST-NORTH POLAND (WE COVER A POPULATION OF 7 MILION PEOPLE)
- COOPERATION WITH THE **PATIENT ADVOCACY GROUPS**
- **VENDORS** RECRUITING PATIENTS



REFFERS NETWORK



PATIENT REFERRAL CENTERS:

Poznan (2 x ward, 4 x outpatient clinic)
Pila (1 x ward, 1 x outpatient clinic)
Pleszew (1 x ward)
Zielona Gora (1 x ward)
Gorzow Wielkopolski (1 x ward)
Szczecin (2 x ward)
Koszalin (1 x ward)
Kolobrzeg (1 x ward)
Bydgoszcz (1 x ward, 1 x outpatient clinic)
Gniezno (1 x outpatient clinic)
Leszno (1 x outpatient clinic)

SUMMARY: 50 hematologists, over 7M people population

HOSPITALIZATION

1. OBSERVATIONAL HOSPITALIZATION FOR STABLE PATIENTS (ON-SITE)

PURPOSE: REQUIRED BY PROTOCOL FOR STABLE PATIENTS UNDER OBSERVATION.

LOCATION: CONDUCTED ON-SITE AT AIDPORT.

2. OBSERVATIONAL HOSPITALIZATION FOR STABLE PATIENTS (HCP HOSPITAL)

PURPOSE: OBSERVATION OF STABLE PATIENTS, WITH PROXIMITY TO THE INTENSIVE CARE UNIT (ICU) FOR SAFETY.

LOCATION: CONDUCTED AT HCP HOSPITAL.

3. HOSPITALIZATION FOR COMPLICATION MANAGEMENT (INTERNAL MEDICINE DEPARTMENT - HCP HOSPITAL)

PURPOSE: MANAGEMENT OF COMPLICATIONS REQUIRING INPATIENT CARE.

LOCATION: INTERNAL MEDICINE DEPARTMENT AT HCP HOSPITAL.

4. INTENSIVE CARE UNIT (ICU) HOSPITALIZATION FOR SEVERE COMPLICATIONS

PURPOSE: TREATMENT OF SEVERE COMPLICATIONS REQUIRING ADVANCED CRITICAL CARE

LOCATION: ICU AT HCP HOSPITAL.



HOSPITALIZATION – HCP HOSPITAL

COLLABORATION WITH HCP HOSPITAL

GUARANTEED ICU AVAILABILITY: OUR CENTER HAS A CONTRACT WITH HCP HOSPITAL, ENSURING ACCESS TO ICU BEDS FOR OUR PATIENTS WHEN NEEDED.

COMPREHENSIVE DIAGNOSTIC AND SURGICAL SERVICES: ON-SITE, HCP HOSPITAL OFFERS A FULL RANGE OF IMAGING DIAGNOSTICS, INCLUDING CT, MRI, AND PET-CT. ADDITIONALLY, A SURGERY DEPARTMENT IS AVAILABLE FOR LIFE-SAVING EMERGENCY OPERATIONS.

EMERGENCY TRANSPORT: TRANSPORT TO HCP HOSPITAL IS PROVIDED BY AMBULANCE. IN URGENT CASES, IT TAKES UP TO 15 MINUTES (14 KM VIA THE SHORTEST ROUTE).

THIS STRUCTURED APPROACH ALLOWS US TO ENSURE OPTIMAL CARE FOR OUR CLINICAL TRIAL PARTICIPANTS AT EVERY LEVEL OF COMPLEXITY.



CONTRACTING PROCESS

- **AVERAGE CONTRACTING TIME:** 2 MONTHS (AGREEMENT & BUDGET FINALIZATION)
- **AGREEMENT TYPE:** TRIPARTITE AGREEMENTS (SPONSOR – SITE – INVESTIGATOR)
- **CONTRACTING APPROACH:**
 - SITE ACCEPTS SPONSOR'S CONTRACT TEMPLATES
 - FRAMEWORK AGREEMENTS IN PLACE WITH MULTIPLE SPONSORS
- **LEGAL SUPPORT:** COLLABORATION WITH AN EXTERNAL LEGAL FIRM
- **BUDGET & PAYMENTS:**
 - 100% OF PAYMENTS GO TO THE INSTITUTION
 - INSTITUTION MANAGES FINANCIAL SETTLEMENTS WITH THE PRINCIPAL INVESTIGATOR AND RESEARCH TEAM
- **REIMBURSEMENT POLICY:** TRAVEL COST REIMBURSEMENTS – PREFERRED VENDOR MODEL



READY FOR YOUR TRIAL

Our commitment to medical excellence is evident through our dedication to conducting clinical trials across **ALL PHASES**, including early, intricate research. We take pride in our ability to tackle **COMPLEX PROCEDURES** and engage in precise, **CHALLENGING RECRUITMENT** efforts. Here, we present four remarkable clinical cases that underscore our commitment to advancing healthcare and pushing the boundaries of medical research.



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