

Meeting dates **23 and 24 October 2017**

Venue **Bayer AG, Müllerstraße 178, 13353 Berlin, Germany**
Building S100, 2nd Floor, Room 002 (auditorium)

Registration at Bayer Bring your passport to register for the General Assembly at the main reception. Your welcome envelope will be handed out in the meeting room.

Timeframe 23 October: Start 10:00 hrs | 24 October: End 15:00 hrs.

WLAN at Bayer HQ Free Wifi available.
Your access data will be sent to your e-mail address by Thursday, October 12, 2017. You will also find a hardcopy in your welcome envelope

Hotel Address **NH Berlin Mitte, Leipziger Str. 106-111, 10117 Berlin, Germany**
Note: The hotel rooms have been booked via Bayer at the NH Hotel as to individual requests upon online registration.

Bayer Contacts

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HARMONY Contact General Assembly

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Programme Summarized

Monday 23rd October, 2017

10.00 - 11.00 **Registration |** At the main reception, passport required!

11.00 - 13.00 **Meaningful Outcomes in HM: Stakeholders' perspectives**

Room: Main building S100, 2nd Floor, Room 002 (Auditorium).

The regulatory agency's perspective on regulatory considerations, on outcome definition and on regulatory-motivated research.

— Michael Steffens, BfArM

Clinical outcomes considered by HTA agencies in reimbursement submission in Europe for HMs drugs.

— Katy Harrison, NICE

Patient associations' perspective on 'neglected outcomes' important for patients.

— Jan Geissler, Leukanet

HARMONY: big data to improve patient outcomes.

— Antonio Palumbo, Takeda

13.00 - 14.00 **Lunch break | Networking | @HARMONY Talks**

14.00 - 14.30 **Keynote Lecture**

Room: Main building S100, 2nd Floor, Room 002 (Auditorium).

Initiatives in big data and hemato-oncology in the US: challenges, lessons learnt, and collaboration opportunities.

— Alan List, Moffit Cancer Center, HARMONY External Advisory Panel

14.45 - 16.15 **WP Meetings: Parallel sessions and Interactions**

First part: around one hour for WP internal update on the progress made and next steps.

Second part: 30 min for targeted meetings on specific questions, such as data governance, outcomes governance, data analytics, and web hosting requirements.

16.15 - 16.30 **Coffee break and Networking**

16.30 - 18.00 **Scientific Cross-Indication Sessions per HM**

AML, NHL, MDs Pilot Projects: status, outcomes definition and next steps.

ALL, NHL, MM, Pediatrics: SOP procedure – Bench-to bedside question, outcomes definition, suggested datasets, analysis modelling, ethical considerations.

19.00 – 21.00 **Networking Dinner at Bayer | @HARMONY Talks**

Tuesday, 24th October 2017

08:00 - 09:00 **HARMONY General Assembly**

Room: Main building S100, 2nd Floor, Room 002 (Auditorium).

Topics:

- First Project Amendment: Updates to the Project Documents (Description of Action, CA and GA): what they are and how this will be implemented.
- Onboarding procedure: How to get involved in the project as Associated Members or new partner. Update on the stakeholders who joined in Year 1.
- Scientific Reporting: Content, process and requirements.
- Risk Management: Assessment of the risks that the project is facing in Year 1 and the plans to manage them.

The GA consists of one appropriately mandated senior representative from each partner who will be entitled to vote on behalf of their organisation. However, any member of the HARMONY Alliance can be present at the meeting and participate in a cooperative manner.

09:00 - 10:00 **HARMONY Platform: data intake procedure and harmonization. Methodologies for OUTCOMES selection & Standard Set Definition**

Room: Main building S100, 2nd Floor, Room 002 (Auditorium).

10:00 - 10:30 **Coffee break and networking**

Room: Main building S100, 2nd Floor, Room 002 (Auditorium).

Learn about the Data Intake process (data de-identification in origin, and data transfer), data harmonization and how the HARMONY Big Data Platform will work.

10:30 - 12:30 **Wrap-Up Session**

Room: Main building S100, 2nd Floor, Room 002 (Auditorium).

Each Work Package Leader will inform of what has been discussed at the WP Meetings, focusing on the aims of their WP in the remaining of the first year, and the second year of HARMONY. Special emphasis will be placed upon WP2: our Key Opinion Leaders will summarise the conclusions reached during each of the Scientific, Cross-Indication HM Sectorial sessions.

12:30 - 13:00 **Roadmap for the next year**

Room: Main building S100, 2nd Floor, Room 002 (Auditorium).

Topics:

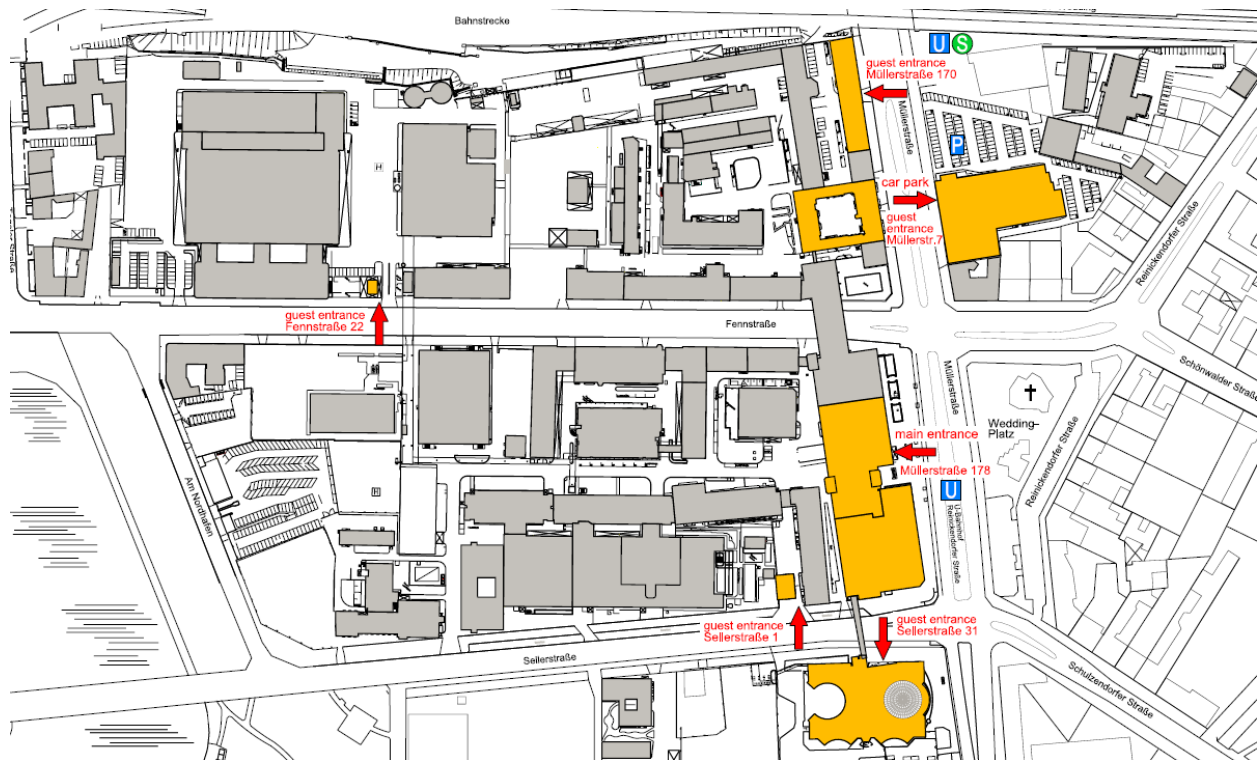
- HARMONY's next steps
- Conclusions from the 2nd General Assembly.

13:15 - 14:45 **Lunch**

Find your way to Bayer

Address

- Bayer AG
- Müllerstraße 178
- 13353 Berlin Germany Tel. +49 30 468 1111
- Please use the main entrance.



Taxi Costs and estimated time

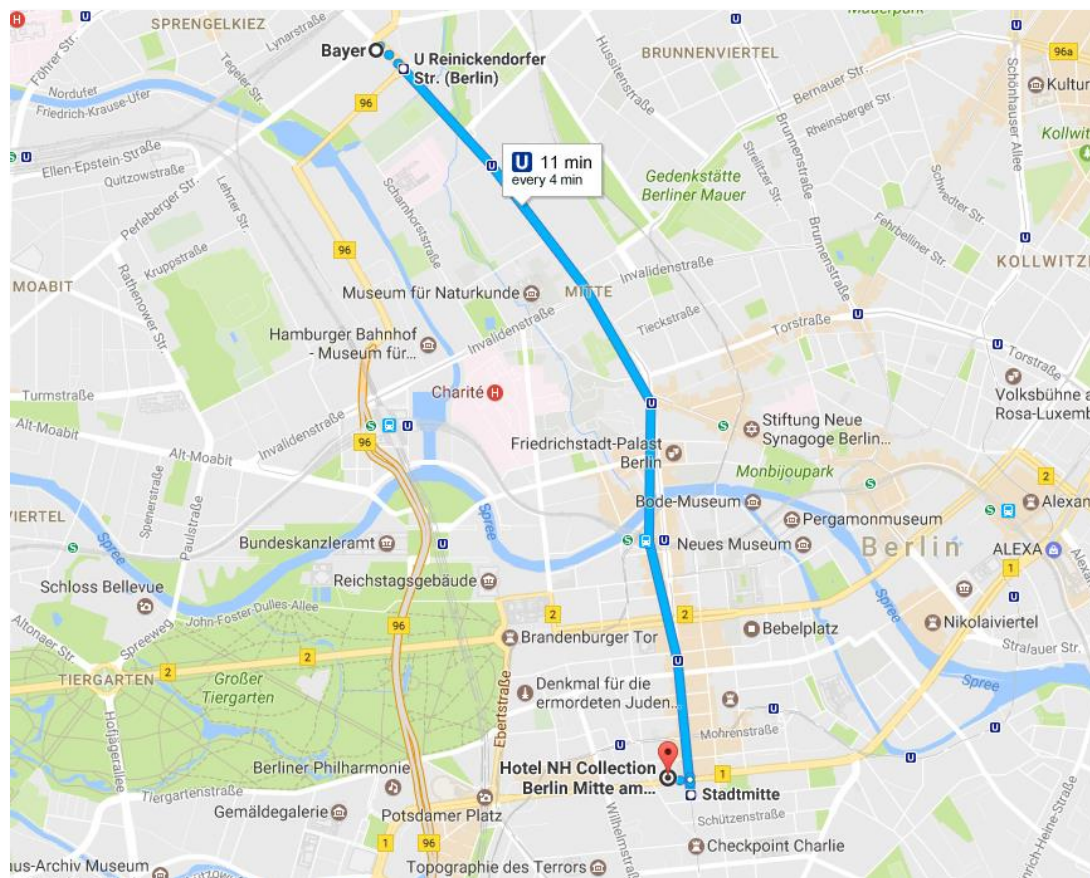
- From Airport Tegel to Bayer approx. 20 € - It will take 20 minutes
- From Airport Schönefeld to Bayer approx. 45 € - It will take 45 minutes

Find your way to the hotel

- The hotel rooms had been booked via Bayer at the NH Hotel as to your individual requests.

NH Berlin Mitte | Leipziger Str. 106-111 | 10117 Berlin, Germany







- The cost for the hotel room is 102 € per night (including breakfast).
- The way from the hotel to Bayer premises: Take the Underground U6 - from Stadtmitte - Direction Alt-Tegel - to Reinickendorfer Straße
- The way from Bayer to the hotel: Take the Underground U6 - from Reinickendorfer Straße - Direction Alt-Mariendorf - to Stadtmitte



- Approx. 10 minutes with public transport and a 3-minute walk

Travelling in Berlin with Public Transportation

from:		Direction	to	Time
Berlin Tegel	128	U Osloer Strasse	U Kurt-Schumacher-Platz	25 min
	6	U Alt-Mariendorf	U Reinickendorfer Strasse	
Berlin Schoenefeld			S Flughafen Schoenefeld	45 min
	RB14	Nauen	S+U Friedrichstrasse	
	6	U Alt-Tegel	U Reinickendorfer Strasse	
Berlin Hauptbahnhof	120	Hainbuchenstrasse	U Reinickendorfer Strasse	6 min

	Airport
	Railway Station
	Bus
	Underground
	Suburban Railway
	change to

Public transport – what does it cost?

ticket	scope	price in €
Day Ticket	Berlin AB	7,00
Day Ticket	Berlin BC	7,40
Day Ticket	Berlin ABC	7,70
Single Ticket	Berlin AB	2,80
Single Ticket	Berlin BC	3,10
Single Ticket	Berlin ABC	3,40
The 4-trip ticket	Berlin AB	9,00

Other information about travelling in Berlin

Berlin AB – for public transport in Berlin
 Berlin ABC – for public transport in Berlin & Brandenburg (including Airport Berlin-Schoenefeld!)

You can find more information about the public transport here:

<http://www.bvg.de/en> or <http://www.bvg.de/en/Tickets/Other-ways-to-buy/At-ticket-machines>