



Our Name is Our Mission!

Annual Work Plan 2021



Overarching objectives

- 1. Experiment simultaneous submission to FDA and EMA**
 - a. Along the recommendations by the JCO publication
 - b. ACCELERATE to advertise (i.e. through EFPIA and Pharma)
 - c. ACCELERATE to disseminate and support any company willing to
 - d. Goal – at least one plan successfully simultaneously submitted and evaluated Feb 2022
- 2. Contribute to shaping the new EU regulatory environment**
 - a. Make publicly available an Executive Summary for each BKS relevant topic, i.e. terminated compounds, incentives and unmet paediatric, needs
 - b. Publish a white paper on facilitated access to terminated compounds
 - c. Monitor the development of the revision process over the next 2 years
 - d. Contribute to public consultations and meetings
- 3. Launch a series of ACCELERATE educational webinars**
- 4. Set-up an ACCELERATE initiative in Australia/New Zealand**
- 5. Explore the regulatory landscape in Japan**

Paediatric strategy forums

1. Two virtual Forums : CAR-T Cells & Tyrosine Kinase Inhibitors in Sarcoma
2. Select the topics of the next three Forums in 2022
3. Publish the Forums' Impact Assessment

Work streams

1. Access Outside Trials

- ✓ Set-up a follow up meeting in April May to deep dive in and propose solutions
- ✓ Publish a White Paper

2. International cooperation

- ✓ Finalise and publish the research paper
- ✓ Launch the survey
- ✓ Define proposed actions
- ✓ Goal : to be presented 2022

3. Fostering Age Inclusive Research (FAIR)

- ✓ Evaluate trials and deliver FAIR Stamps

4. Fit for filing

- ✓ Produce and publish best principles guidelines

5. Long term follow up

- ✓ Finalise the project to be approved by the Steering Committee
- ✓ Move into the implementation phase, reshaping participants and leadership

6. Real Word Evidence

- ✓ Publish a white paper



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