

## TRANSLATIONAL ASSESSMENT WORKSHOP

## AGENDA

| Time                              | Wednesday 07 October, 13.30 – 17.30  | Moderator                  |  |
|-----------------------------------|--|----------------------------|--|
| 13.30                             | Welcome and coffee – presentation agenda   | Florence Bietrix           |  |
| TRANSLATIONAL ASSESSMENT WORKSHOP |  |                            |  |
| 13.45                             | - General introduction TA  | Anton Ussi                 |  |
| 14.00                             | <ul> <li>Drug development – reverse planning for success</li> </ul>  | Bernd Eisele               |  |
| 14.30                             | <ul> <li>Navigating the regulatory maze</li> </ul>   | Giovanni Migliaccio        |  |
| 15.00                             | - IP – A necessary evil?   | Anton Ussi – Tim Moser     |  |
| 15.20                             | Break  |                            |  |
| 15.40                             | - HTA as early as possible?  | Umberto Restelli           |  |
| 16.00                             | <ul> <li>EATRIS Translational assessment service to support<br/>translational feasibility of projects – an overview</li> </ul> | Florence Bietrix<br>Martin |  |
| 16.20                             | Kick-off use case group work (4 groups)  | Florence Bietrix           |  |
| 16.30                             | Use case – group work  | Parallel sessions          |  |
| 17.30                             | End – day 1 – remote drinks and chat   |                            |  |

| Time          | Thursday 08 October, 09.30 – 12.30     | Moderator         |  |
|---------------|--|-------------------|--|
| 09.30         | Welcome and coffee                     | Florence Bietrix  |  |
| 09.45         | Use case – group work                  | Parallel sessions |  |
| 10.15         | Presentation use cases (4 x 10 min)    |                   |  |
| 11.00         | Discussion – Looking forward           | Anton Ussi        |  |
| 11.30         | Coffee Break                           |                   |  |
| EATRIS UPDATE |  |                   |  |
| 11.50         | Update EATRIS-Plus/ NC Role            | Eliis Keidong     |  |
| 12.30         | HE Work Programme – building synergies | Anne-Charlotte    |  |
| 13.00         | End                                    |                   |  |

<u>Use cased - 4 working groups:</u>

- Unmet medical need and standard of care
- IP, competitive landscape and market
- End-product classification and regulatory strategy
- Translational strategy and project management

Resources to be made available:

- Use case description (business plan)
- EATRIS Digital Resources
- GlobalData
- RIS

