# INCAS Report

## May 2020

## Key variables of report:

**Recruitment**

| | | |
|---|---|---|
| Enrolled: | 444 subjects | |
| Drop-out at 3 months: | 39% | (35% when adjusting for inactive sites) |
| Drop-out at 9 months: | 56% | (52% when adjusting for inactive sites) |

**Missing data (Oct-19)**

| | |
|---|---|
| Patient files (treatment, sociodemographics, co-morbidities): | Close to 0 % |
| Baseline patient interview (TLFB, CGI and self-rating scales): | appr. 5% |
| 3-months patient interview: | 6-10% |
| 9-months patient interview: | 5-10% |

## 8 currently active sites:

Sweden, Schweiz, Netherlands, Brussels, Antwerp, Hungary, Spain, Frankfurt

## 3 currently inactive sites:
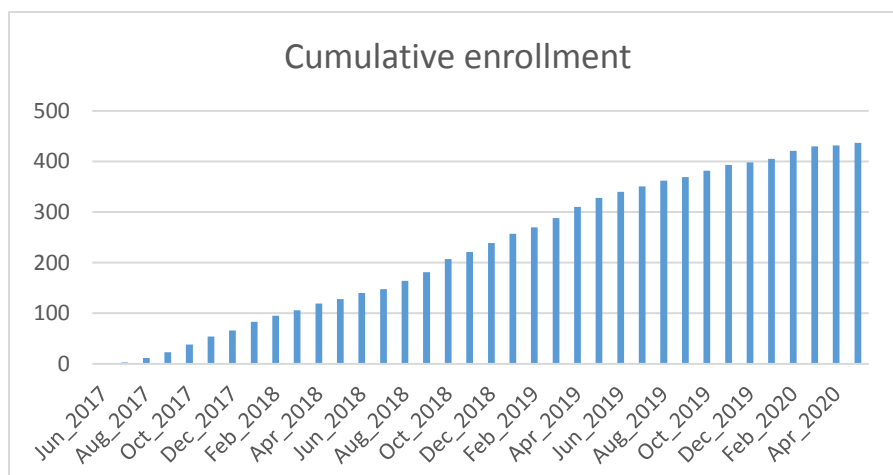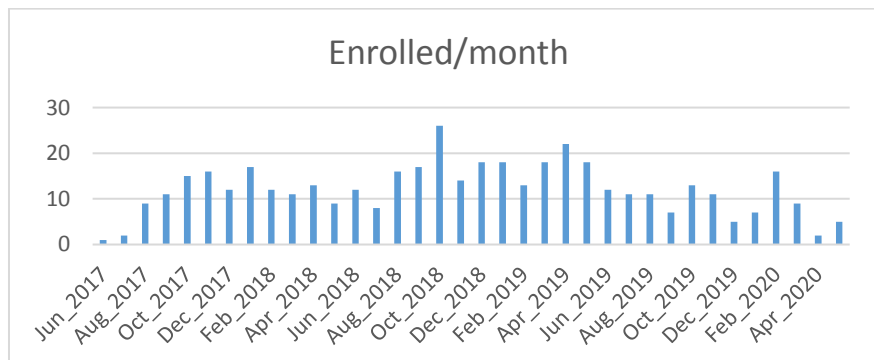
Syracuse, Mount Sinai and Mannheim.

## 3 new sites that might start this year:

Oslo, France and Australia.

## Progress

| INCAS – all sites (n = 11) | | Expected | actual/expected | Drop-out |
|---|---|---|---|---|
| Enrolled | 444 | | | |
| 4 weeks | 384 | 436 | 0,88 | 12% |
| 3 months | 244 | 400 | 0,61 | 39% |
| 9 months | 149 | 339 | 0,44 | 56% |
| Enrolled/month | 12 | | | |
| Enrolled/month 2017 | 9 | | | |
| Enrolled/month 2018 | 14 | | | |
| Enrolled/month 2019 | 13 | | | |
| Enrolled/month Jan2020-Apr2020 | 9 | | | |

| INCAS – active sites (n = 9) | | Expected | actual/expected | Drop-out |
|---|---|---|---|---|
| Enrolled | 402 | | | |
| 4 weeks | 352 | 394 | 0,89 | 11% |
| 3 months | 234 | 358 | 0,65 | 35% |
| 9 months | 144 | 297 | 0,48 | 52% |

## Missing data (Oct 2019)

The numbers below can be either a completely missing form or just one missing item in a form.

Note that there was an previously undetected systematic error in the Dutch eCRF where item 22 was missing. This affected all sites in Belgium and Netherland and was detected in the end of 2018.

| Missing data – all sites (n =12) | Baseline | 4weeks | 3 months | 9 months |
|---|---|---|---|---|
| TLFB (%) | 5,26% | - | 6,20% | 1,41% |
| EQ5D (%) | 3,56% | - | 10,52% | 10,10% |
| Self-Efficacy  (%) | 4,05% | - | 8,64% | 9,68% |
| ASRS part 1  (%) | 5,40% | - | 7,17% | 4,42% |
| ASRS part 2  (%) | 23,06% | - | 10,92% | 4,42% |
| CGI | 7,00% | - | 9,35% | 9,09% |
| ASRS part 2 (Dutch eCRF excluded) | 3,16% | | | |

Key outcome data from patient files (comorbidities, sociodemographics, treatments and so on) basically do not have any missing data.

## Site Specifics

| Spain | | Exp | actual/exp |
|---|---|---|---|
| Active | Yes | | |
| Enrolled | 22 | | |
| 4 weeks | 15 | 22 | 0,68 |
| 3 months | 12 | 22 | 0,55 |
| 9 months | 7 | 12 | 0,58 |
| Last recruitment | Nov 2019 | | |

| Frankfurt | | Expected | actual/exp |
|---|---|---|---|
| Active | Yes | | |
| Enrolled | 27 | | |
| 4 weeks | 26 | 26 | 1,00 |
| 3 months | 15 | 23 | 0,65 |
| 9 months | 5 | 14 | 0,36 |
| Last recruitment | Mar 2020 | | |

| Hungary | | Expected | actual/exp | |
|---|---|---|---|---|
| Active | Yes | | | |
| Enrolled | 11 | | | |
| 4 weeks | 9 | 11 | 0,82 | |
| 3 months | 8 | 10 | 0,8 | |
| 9 months | 3 | 5 | 0,6 | |
| Last recruitment | July 2019 | | | |

| Netherlands | | Exp | actual/exp |
|---|---|---|---|
| Active | Yes | | |
| Enrolled | 64 | | |
| 4 weeks | 60 | 64 | 0,94 |
| 3 months | 31 | 60 | 0,5 |
| 9 months | 18 | 54 | 0,33 |
| Last recruitment | Mar 2020 | | |

| Switzerland | | Exp | actual/exp |
|---|---|---|---|
| Active | Yes | | |
| Enrolled | 116 | | |
| 4 weeks | 102 | 116 | 0,88 |
| 3 months | 73 | 109 | 0,7 |
| 9 months | 55 | 102 | 0,54 |
| Last recruitment | Mar 2020 | | |

| Sweden | | Exp | actual/exp |
|---|---|---|---|
| Active | Yes | | |
| Enrolled | 104 | | |
| 4 weeks | 90 | 97 | 0,93 |
| 3 months | 66 | 83 | 0,8 |
| 9 months | 41 | 71 | 0,58 |
| Last recruitment | May 2020 | | |

| Antwerp | | Exp | actual/exp |
| --- | --- | --- | --- |
| Active | Yes | | |
| Enrolled | 35 | | |
| 4 weeks | 35 | 35 | 1,00 |
| 3 months | 20 | 30 | 0,7 |
| 9 months | 11 | 27 | 0,41 |
| Last recruitment | Feb 2020 | | |

| Brussels | | Exp | actual/exp |
| --- | --- | --- | --- |
| Active | Yes | | |
| Enrolled | 23 | | |
| 4 weeks | 15 | 23 | 0,65 |
| 3 months | 9 | 21 | 0,4 |
| 9 months | 4 | 12 | 0,33 |
| Last recrutiment | Feb 2020 | | |

| Mount Sinai | | Expected | actual/exp | |
| --- | --- | --- | --- | --- |
| Active | No | | | |
| Enrolled | 3 | | | |
| 4 weeks | 2 | 3 | 0,67 | |
| 3 months | 2 | 3 | 0,7 | |
| 9 months | 0 | 0 | 0,00 | |
| Last recruitment | 2019 | | | |

| Syracuse | | Expected | actual/exp | |
| --- | --- | --- | --- | --- |
| Active | No | | | |
| Enrolled | 24 | | | |
| 4 weeks | 8 | 24 | 0,33 | |
| 3 months | 3 | 24 | 0,1 | |
| 9 months | 2 | 24 | 0,08 | |
| **Last recruitment 2018** | | | | |

| Mannheim | | Expected | actual/exp | |
| --- | --- | --- | --- | --- |
| Active | No | | | |
| Enrolled | 15 | | | |
| 4 weeks | 8 | 15 | 0,53 | |
| 3 months | 5 | 15 | 0,3 | |
| 9 months | 1 | 15 | 0,07 | |
| Last recruitment | June 2018 | | | |