Switching to an infliximab biosimilar

Exploring the reasons behind the substantial discontinuation rate in patients undergoing CT-P13 in a large tertiary hospital in Western Switzerland: a retrospective cohort study using routinely collected medical data.

Drugs – Real World Outcomes

Marko KRSTIC a, b, c, d, Jean-Christophe DEVAUD b, c, Joachim MARTI e, f, Farshid SADEGHIPOUR a, b, c, d

a Institute of Pharmaceutical Sciences of Western Switzerland, University of Geneva, University of Lausanne
b Service of Pharmacy, Lausanne University Hospital and University of Lausanne
c Center for Research and Innovation in Clinical Pharmaceutical Sciences, Lausanne University Hospital and University of Lausanne
d School of Pharmaceutical Sciences, University of Geneva
e University of Lausanne, Faculty of Biology and Medicine, Lausanne, VD, CH
f Centre for Primary Care and Public Health (Unisanté), Lausanne VD, CH

Corresponding author address: Farshid SADEGHIPOUR, Section de Pharmacie, Quartier UNIL-Sorge, Bâtiment Génopode CH-1015 Lausanne, Suisse, Farshid.Sadeghipour@unil.ch, +41 79 556 32 30, ORCID ID: 0000-0003-0817-5393

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I. Variables and data sources/measurements

Variables’ source of data, their definition, details of the methods of assessment, and statistical analyses are listed in Table I.

Table I: Variables’ sources of data, definitions and methods of assessment (measurement).

| Variable                                      | Sources of data | Definition and measurement                                                                                                                                 |
|-----------------------------------------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of birth                                 | 1, 2, 5         | Patients’ year of birth. Age was calculated as of December 31, 2020 and analyzed using the Wilcoxon rank Sum test for non-normally distributed data.       |
| Gender                                        | 1, 2, 5         | Patients’ gender, either “male” or “female”.                                                                                                             |
| Date of switching to another treatment        | 1, 2, 3, 4, 5   | The date of switching to another treatment was considered to be the first day of administration of the new treatment. When not available, the date of switching was set to the 15th day of the month of treatment. |
| Diagnoses                                     | 1, 2, 5         | Diagnoses were classified in three categories: rheumatological (ankylosing spondylitis, juvenile arthritis, psoriatic arthritis and rheumatoid arthritis), gastroenterological (Crohn’s disease and ulcerative colitis) and immunological (Behçet's disease, Cogan’s syndrome, hidradenitis, psoriasis, pyoderma gangrenosum, sarcoidosis and uveitis). Diagnoses were taken as is from the various sources of data available. |
| End of treatment                              | 1, 2, 3, 5      | The last day of administration was considered to be the end of treatment. When not available, the last day of administration was set to the 15th day of the last month of treatment administration. |
| Number of biologics pre-/post-infliximab/CT-P13 treatment | 1, 2, 3, 5 | Any biologic treatment used to treat the patient’s before/after OI/CT-P13 treatment, including: TNF-α inhibitors (adalimumab, certolizumab, etanercept, golimumab, infliximab), interleukin inhibitors (guselkumab, ixekizumab, risankizumab, secukinumab, tildrakizumab, tocilizumab, ustekinumab) and selective immunosuppressants (vedolizumab). The association between the number of biologics tried before CT-P13 treatment and CT-P13 discontinuation was analyzed using logistic regressions models (Online Resource 3). |
| Time of exposure (TOE) to a treatment         | 1, 2, 3, 4      | For a particular treatment, time of exposure was calculated as the difference between end of treatment and treatment onset. CT-P13 treatment persistence was plotted using Kaplan-Meier plots and analyzed using the non-parametric Log-rank test (Online Resource 3). |
| Reasons for treatment discontinuation (RTDs)  | 1, 2, 3, 4, 5   | When the reasons for treatment discontinuation (RTDs) were not explicit, or not clinically assessed, TOE was used to decide between lack of efficacy (TOE < 180 days) and secondary loss of response (TOE > 180 days). Other RTDs involved adverse events, ambulatory relay (due to the patient’s desire for more autonomy), acute systemic reaction, pregnancy and remission. When no information was available, the RTD was unknown. |
| Status                                        | 1, 2, 3, 4      | Switchee were patients that were on OI treatment for ≥ 3 months before their switch to CT-P13. Initiators were patients that did not receive OI prior to CT-P13 treatment. |
| Treatment exposure                            | 1, 2, 3, 4      | When not explicit (e.g. infusion protocols not available), prior drug exposure was assumed based on information available in the patients’ medical records. |
| Treatment onset                               | 1, 2, 3, 4      | The first day of administration was considered to be the treatment onset. When not available, the first day of administration was set to the 15th day of the first month of treatment administration. |

1 correspondence between referring physicians and other specialists  
2 discharge letters  
3 infusion protocols completed during the administration of biological drugs  
4 laboratory blood test results  
5 physician and nursing notes

CRP = C-reactive protein, ESR = Erythrocyte sedimentation rate, OI = Originator infliximab, TNF-α = Tumor necrosis factor-α
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II. CASE REPORT FORM

Name of the investigator: .......................................................... Date: ........................

I. Patient specific information
I.1. Date of birth: ..........................................................................................................................
I.2. Gender: ..................................................................................................................................
I.3. Primary diagnosis: ....................................................................................................................
I.4. Number of previous biologics: .................................................................................................

II. Treatment specific information
II.1. Treatment as of 31.12.2020: .....................................................................................................
II.2. Date of 1st Remicade infusion: ...............................................................................................-
II.3. Date of last Remicade infusion: ..............................................................................................
II.4. Was the patient switched from Remicade to Inflectra: .........................................................
II.5. Date of 1st Inflectra infusion: ................................................................................................
II.6. Observations on the 1st day of Inflectra infusion: ..................................................................
II.7. Observations following the 1st day of Inflectra infusion and before the 2nd Inflectra infusion: ...
II.8. Date of 2nd Inflectra infusion: ...............................................................................................-
II.9. Observations on 2nd day of Inflectra infusion: ......................................................................
II.10. Observations following the 2nd day of Inflectra infusion and before the last Inflectra infusion:
II.11. Date of last Inflectra infusion: .............................................................................................
II.12. Reasons for Inflectra discontinuation: ................................................................................

III. Following treatment (Inflectra + 1, 2, 3, ..., n) specific information
III.1. n of (Inflectra + n): ..................................................................................................................
III.2. Name of (Inflectra + n): ..........................................................................................................-
III.3. Date of 1st administration of (Inflectra + n): .........................................................................
III.4. Observations on the 1st day of (Inflectra + n): ....................................................................
III.5. Date of last (Inflectra + n) administration: ............................................................................
III.6. Observations during the interval between the 1st and last (Inflectra + n) administration:...
III.7. n of (Inflectra + n): ..................................................................................................................
III.8. Name of (Inflectra + n): ..........................................................................................................
III.9. Date of 1st administration of (Inflectra + n): .........................................................................
III.10. Observations on the 1st day of (Inflectra + n): ....................................................................
III.11. Date of last (Inflectra + n) administration: ............................................................................
III.12. Observations during the interval between the 1st and last (Inflectra + n) administration:...
III.13. n of (Inflectra + n): ..................................................................................................................
III.14. Name of (Inflectra + n): ..........................................................................................................
III.15. Date of 1st administration of (Inflectra + n): .........................................................................
III.16. Observations on the 1st day of (Inflectra + n): ....................................................................
III.17. Date of last (Inflectra + n) administration: ............................................................................
III.18. Observations during the interval between the 1st and last (Inflectra + n) administration:...
III.19. n of (Inflectra + n): ..................................................................................................................
III.20. Name of (Inflectra + n): ..........................................................................................................
III.21. Date of 1st administration of (Inflectra + n): .........................................................................
III.22. Observations on the 1st day of (Inflectra + n): ....................................................................
III.23. Date of last (Inflectra + n) administration: ............................................................................
III.24. Observations during the interval between the 1st and last (Inflectra + n) administration:...
### III. Population’s characteristics

Table II: Baseline characteristics of the patients included in the study detailed by diagnosis group (rheumatological, gastroenterological or immunological) and by status (switcher or initiator). Percentages have been rounded upwards and only serve as an indicative purpose.

| All patients included | GAS (n = 67) | RHE (n = 61) | IMM (n = 28) | Total (n = 156) |
|----------------------|--------------|--------------|--------------|----------------|
| Female               | n (%)        | n (%)        | n (%)        | n (%)          |
| n of patient that discontinued CT-P13 at 6 months | 34 (51) | 28 (46) | 17 (61) | 79 (51) |
| n of patient that discontinued CT-P13 at 12 months | 27 (40) | 25 (41) | 6 (21) | 58 (37) |
| Switchers            | n (%)        | n (%)        | n (%)        | n (%)          |
| Female               | n (%)        | n (%)        | n (%)        | n (%)          |
| n of previous biologic drugs | 21 (62) | 17 (41) | 5 (50) | 43 (51) |
| n of following biologic drugs | 0-2 | 0-3 | 0-2 | 0-3 |
| OI duration before switch to CT-P13 | 3 (2-5) | 8 (4-12) | 6 (5-9) | 5 (3-10) |
| n of patient that discontinued CT-P13 at 6 months | 3 (9) | 10 (24) | 1 (10) | 14 (16) |
| n of patient that discontinued CT-P13 at 12 months | 7 (21) | 14 (34) | 2 (20) | 23 (27) |
| CT-P13 duration before discontinuation at 6 months | 0 (0-28) | 55 (33-80) | 104 (84-135) | 63 (39-107) |
| CT-P13 duration before discontinuation at 12 months | 211 (28-237) | 81 (50-228) | 135 (94-181) | 117 (55-214) |
| Initiators           | n (%)        | n (%)        | n (%)        | n (%)          |
| Female               | n (%)        | n (%)        | n (%)        | n (%)          |
| n of previous biologic drugs | 18 (55) | 10 (50) | 8 (44) | 36 (51) |
| n of following biologic drugs | 0-1 | 0-5 | 0-4 | 0-5 |
| n of patient that discontinued CT-P13 at 6 months | 13 (39) | 8 (40) | 2 (11) | 23 (32) |
| n of patient that discontinued CT-P13 at 12 months | 20 (61) | 11 (55) | 4 (22) | 35 (49) |
| CT-P13 duration before discontinuation at 6 months | 42 (38-136) | 92 (69-97) | 123 (106-133) | 92 (42-123) |
| CT-P13 duration before discontinuation at 12 months | 142 (42-194) | 99 (91-200) | 142 (123-199) | 123 (57-202) |

CI = Confidence interval at 95%, GAS = Gastroenterological diagnosis group, IMM = Immunological diagnosis group, IQR = Interquartile range, n = number, RHE = Rheumatological diagnosis group, OI = Originator infliximab
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IV. Further analysis

IV.1. Age distribution of the included patients

Table III: Median age of the included patients by diagnosis group, disease and status.

| Diagnosis group     | Disease                        | n (Age) | Switcher | Initiator |
|---------------------|--------------------------------|---------|----------|-----------|
| Rheumatological     | Ankylosing spondylitis         | 25 (53) | 8 (46)   |           |
|                     | Juvenile arthritis             | 1 (24)  | 3 (19)   |           |
|                     | Psoriatic arthritis            | 7 (52)  | 3 (47)   |           |
|                     | Rheumatoid arthritis           | 8 (70)  | 6 (51)   |           |
| Gastroenterological | Crohn's Disease                | 20 (31) | 21 (24)  |           |
|                     | Ulcerative colitis             | 14 (27) | 12 (28)  |           |
|                     | Behçet's disease               | 5 (50)  | 4 (41)   |           |
|                     | Cogan's syndrome               | –       | 1 (43)   |           |
|                     | Hidrosadenitis                 | –       | 2 (34)   |           |
| Immunological       | Psoriasis                      | 2 (46)  | 1 (53)   |           |
|                     | Pyoderma gangrenosum           | –       | 2 (67)   |           |
|                     | Sarcoidosis                    | 2 (42)  | 6 (57)   |           |
|                     | Uveitis                        | 1 (73)  | 2 (30)   |           |

n = number of patients

Table IV: Median age and interquartile range of the included patients by diagnosis group, status, and gender.

| Diagnosis group     | Status      | Gender | Number of patients | Age (interquartile range) |
|---------------------|-------------|--------|--------------------|--------------------------|
| Rheumatological     | Switcher    | Male   | 24 (15)            | 56 (13)                  |
|                     |             | Female | 17 (11)            | 55 (22)                  |
|                     | Initiator   | Male   | 10 (6)             | 46 (17)                  |
|                     |             | Female | 10 (6)             | 31 (22)                  |
|                     | Switcher    | Male   | 13 (8)             | 25 (32)                  |
|                     |             | Female | 21 (13)            | 29 (19)                  |
|                     | Initiator   | Male   | 15 (10)            | 26 (25)                  |
|                     |             | Female | 18 (12)            | 26 (15)                  |
|                     | Switcher    | Male   | 5 (3)              | 35 (25)                  |
|                     |             | Female | 5 (3)              | 56 (20)                  |
|                     | Initiator   | Male   | 10 (6)             | 51 (26)                  |
|                     |             | Female | 8 (5)              | 40 (19)                  |

Fig. I: Age of the patients included in the study by diagnosis group and patient status. *** = p-value < 0.001 (Wilcoxon Rank Sum Test)
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Table V: Statistical significance of the difference in median age among patients, by diagnosis group and patient status (Wilcoxon Rank Sum Test).

| Diagnosis group        | Status 1   | Status 2   | p - value |
|------------------------|------------|------------|-----------|
| Rheumatological        | Switchers  | Initiators | 9.80E-04  |
| Gastroenterological    | Switchers  | Initiators | 0.58      |
| Immunological          | Switchers  | Initiators | 0.91      |

Fig. II: Age of the patients included in the study by diagnosis group, patient status and faceted by gender. IMM = Immunological diagnosis group, GAS = Gastroenterological diagnosis group, RHE = Rheumatological diagnosis group. ** = p-value < 0.01 (Wilcoxon Rank Sum Test)

Table III: Statistical significance of the difference in median age among patients, by diagnosis group and patient status, for Gender = ”Female” (Wilcoxon Rank Sum Test).

| Diagnosis group        | Status 1   | Status 2   | p - value |
|------------------------|------------|------------|-----------|
| Rheumatological        | Switchers  | Initiators | 2.20E-03  |
| Gastroenterological    | Switchers  | Initiators | 0.85      |
| Immunological          | Switchers  | Initiators | 0.14      |
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IV.2. Primary conditions of the patients included in the study

![Graph showing primary conditions of patients per diagnosis group and patient status.]

**Fig. III** Primary conditions of the patients included in the study, per diagnosis group and patient status.

IV.3. Ratio analysis of the patients in each group

The statistical tests used to compare the two cohorts for qualitative purpose are listed in Table VII.

**Table VII**: Further statistical analysis used to characterize the patients’ population.

| Variable                                      | Statistical test                     | Result                                                                 | p-value |
|-----------------------------------------------|--------------------------------------|------------------------------------------------------------------------|---------|
| Sex ratio between initiators and switchers   | Accept $H_0$ → Proportion of female is not significantly different between initiators and switchers | 1           |         |
| GAS patients ratio initiators and switchers  | Accept $H_0$ → Proportion of GAS patients is not significantly different between initiators and switchers | > 0.05     |         |
| RHE patients ratio between initiators and switchers | Two-proportions Z-test Reject $H_0$ → Proportion of GAS patients is significantly different between initiators and switchers | < 0.02     |         |
| IMM patients ratio between initiators and switchers | Reject $H_0$ → Proportion of GAS patients is significantly different between initiators and switchers | > 0.05     |         |
| Number of biologics tried before CT-P13 switch | Wilcoxon rank sum test (non-parametric) Accept $H_0$ → Median number of biologics tried before CT-P13 switch is not significantly different between initiators and switchers for GAS (>0.05), IMM (>0.05) or RHE (>0.05). | > 0.05*    |         |
| Number of biologics tried after CT-P13 switch | Reject $H_0$ → Median number of biologics tried after CT-P13 switch is significantly different between initiators and switchers | < 0.01*    |         |

GAS = Gastroenterological diagnosis group, $H_0 =$ Null hypothesis, IMM = Immunological diagnosis group, switchers = Non-naive patients, initiators = Non-naive patients, RHE = Rheumatological diagnosis group

* all diagnosis group combined
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IV.4. Association between the number of biologics tried before CT-P13 and CT-P13 discontinuation

![Graph showing the association between the number of biologics tried before CT-P13 treatment and CT-P13 discontinuation.](image)

**Fig. IV** Visual assessment of the association between the event CT-P13 discontinuation (0 = no discontinuation, 1 = discontinuation) and the variable “more than 1 biologic before CT-P13 treatment” (0 = 0 or 1 biologic before CT-P13 treatment, 1 = more than 1 biologic before CT-P13 treatment). The regression line is fitted using a generalized linear model with a binomial error distribution and serves only an aesthetic purpose. Jittering has been added to the scatter plot in order to prevent overplotting and serves only an aesthetic purpose.

**Table IVIII:** Risks of CT-P13 discontinuation.

|                        | 1 biologic or less before CT-P13 | 2 biologics or more before CT-P13 | Total |
|------------------------|----------------------------------|-----------------------------------|-------|
| No CT-P13 discontinuation | 83                               | 13                                | 96    |
| CT-P13 discontinuation  | 50                               | 10                                | 60    |
| Total                  | 133                              | 23                                | 156   |
| Risk                   | 0.38                             | 0.43                              | 0.38  |
| Risk difference (attributable risk) | 0.06                             | -0.16                             | 0.25  |
| Risk ratio             | 1.16                             | 0.44                              | 3.02  |

Chi-squared (d.f. = 1)  
Fisher's exact test (2-sided)  
p-value = 0.5922  
p-value = 0.6457

\[CI = \text{Confidence Interval, d.f. = degrees of freedom}\]
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Table IX: Logistic regression model using the variable “More_than_1” and comparison with the null model.

|             | Estimate | Std. Error | z value | Pr(|z|) |
|-------------|----------|------------|---------|---------|
| (Intercept) | -0.5068  | 0.179      | -2.831  | 0.00464 |
| More_than_1 | 0.2445   | 0.4571     | 0.535   | 0.59282 |

| Model       | Df       | Deviance Resid. | Resid. Dev | Pr(>Chi) |
|-------------|----------|-----------------|------------|----------|
| NULL        | 155      | 0.2835          | 207.88     | 0.5944   |
| More_than_1 | 154      | 0.2835          | 207.59     | 0.5944   |

Pr(>Chi) = p-value of the Likelihood-ratio test used to test the null hypothesis (H₀) that both models have the same performance for predicting CT-P13 discontinuation,

Pr(|z|) = p-value used to test the null hypothesis (H₀) that the corresponding parameter is zero,

z value = Wald statistic

Fig. V Visual assessment of the association between CT-P13 discontinuation (0 = no discontinuation, 1 = discontinuation) and the number of biologics tried before treatment with original infliximab (OI) or CT-P13, stratified per diagnosis groups. The regression lines are fitted using a generalized linear model with a binomial error distribution and serve only an aesthetic purpose. Jittering has been added to the scatter plot in order to prevent overplotting and serves only an aesthetic purpose.
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Table X: Risks of CT-P13 discontinuation, based on the number of biologics tried before OI or CT-P13 for the rheumatology diagnosis group.

|                | 1 biologic or less before CT-P13 | 2 biologics or more before CT-P13 | Total |
|----------------|----------------------------------|-----------------------------------|-------|
| No CT-P13 discontinuation | 26                              | 10                                | 36    |
| CT-P13 discontinuation     | 18                              | 7                                 | 25    |
| Total                      | 44                              | 17                                | 61    |
| Risk                       | 0.41                            | 0.41                              | 0.41  |

Risk difference (attributable risk) Estimate Lower 95 CI Upper 95 CI
0.39 0.39 0.92 0.03
Risk ratio 1.01 0
Chi-squared (d.f. = 1) p-value = 0.9848
Fisher's exact test (2-sided) p-value = 1

CI = Confidence Interval, d.f. = degrees of freedom, Inf = Infinity

Table XI: Logistic regression model using the variable “More_than_1” and comparison with the null model, for the rheumatology diagnosis group.

|                | Estimate | Std. Error | z value | Pr(>|z|) | Df  | Deviance Resid. | Df  | Resid. Dev | Pr(>|Chi|) |
|----------------|----------|------------|---------|----------|-----|-----------------|-----|-------------|----------|
| (Intercept)    | 0.36772  | 0.30662    | -1.199  | 0.230    | 0   | 0.0036234       | 0   | 0.00036234  | 0.9848   |
| More_than_1TRUE| 0.01105  | 0.58041    | 0.019   | 0.985    | 1   | 82.569          | 59  | 82.569      | 0.9848   |

Pr(>|Chi|) = p-value of the Likelihood-ratio test used to test the null hypothesis (H0) that both models have the same performance for predicting CT-P13 discontinuation,
Pr(>|z|) = p-value used to test the null hypothesis (H0) that the corresponding parameter is zero,
z value = Wald statistic

Table XII: Risks of CT-P13 discontinuation, based on the number of biologics tried before OI or CT-P13 for the gastroenterology diagnosis group.

|                | 1 biologic or less before CT-P13 | 2 biologics or more before CT-P13 | Total |
|----------------|----------------------------------|-----------------------------------|-------|
| No CT-P13 discontinuation | 40                              | 1                                 | 41    |
| CT-P13 discontinuation     | 26                              | 0                                 | 26    |
| Total                      | 66                              | 1                                 | 67    |
| Risk                       | 0.39                            | 0                                 | 0.39  |

Risk difference (attributable risk) Estimate Lower 95 CI Upper 95 CI
-0.39 -0.92 -0.03
Risk ratio 0 0
Chi-squared (d.f. = 1) p-value = 0.4224*
Fisher's exact test (2-sided) p-value = 1

CI = Confidence Interval, d.f. = degrees of freedom, Inf = Infinity
* Chi-squared approximation may be incorrect
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**Table XIII**: Logistic regression model using the variable “More_than_1” and comparison with the null model, for the gastroenterology diagnosis group.

|                         | Estimate   | Std. Error | z value | Pr(>|z|) |
|-------------------------|------------|------------|---------|----------|
| (Intercept)             | -0.4308    | 0.2519     | -1.71   | 0.0873   |
| More_than_1TRUE         | -15.1353   | 1455.3976  | -0.01   | 0.9917   |
| **NULL**                |            |            |         |          |
| More_than_1             |            |            |         |          |

**Df** | Deviance Resid. | **Df** | Resid. Dev | **Pr(>|Chi|)**
--- | --- | --- | --- | ---
NULL | | | | 89.495
More_than_1 | | | 88.503 | 0.3193

*Pr(>|Chi|) = p-value of the chi-squared test used to test the null hypothesis (H₀) that both models have the same performance for predicting CT-P13 discontinuation,
Pr(>|z|) = p-value used to test the null hypothesis (H₀) that the corresponding parameter is zero,
z value = Wald statistic

**Table XIV**: Risks of CT-P13 discontinuation, based on the number of biologics tried before OI or CT-P13 for the immunology diagnosis group.

|                              | 1 biologic or less before CT-P13 | 2 biologics or more before CT-P13 | Total |
|------------------------------|----------------------------------|----------------------------------|-------|
| No CT-P13 discontinuation    | 17                               | 2                                | 19    |
| CT-P13 discontinuation       | 6                                | 3                                | 9     |
| Total                        | 23                               | 5                                | 28    |
| Risk                         | 0.26                             | 0.6                              | 0.32  |

**Risk difference (attributable risk)** | **Lower 95 CI** | **Upper 95 CI**
--- | --- | ---
0.34 | -0.12 | 0.61
Risk ratio | 2.3 | 0.41 | 12.98
Chi-squared (d.f. = 1) | p-value = 0.1411*
Fishers exact test (2-sided) | p-value = 0.2901

* CI = Confidence Interval, d.f. = degrees of freedom, Inf = Infinity
* Chi-squared approximation may be incorrect

**Table XV**: Logistic regression model using the variable “More_than_1” and comparison with the null model, for the immunology diagnosis group.

|                         | Estimate   | Std. Error | z value | Pr(>|z|) |
|-------------------------|------------|------------|---------|----------|
| (Intercept)             | -1.0415    | 0.4749     | -2.193  | 0.0283   |
| More_than_1TRUE         | 1.4469     | 1.029      | 1.406   | 0.1597   |
| **NULL**                |            |            |         |          |
| More_than_1             |            |            |         |          |

**Df** | Deviance Resid. | **Df** | Resid. Dev | **Pr(>|Chi|)**
--- | --- | --- | --- | ---
NULL | | | 35.165
More_than_1 | | | 33.132 | 0.154

*Pr(>|Chi|) = p-value of the Likelihood-ratio test used to test the null hypothesis (H₀) that both models have the same performance for predicting CT-P13 discontinuation,
Pr(>|z|) = p-value used to test the null hypothesis (H₀) that the corresponding parameter is zero,
z value = Wald statistic
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IV.5. CT-P13 persistence over time, per diagnosis group

Fig. VI Kaplan-Meier plot showing the proportion of switchers (yellow) and initiators (blue) that discontinued CT-P13 over 360 days, by diagnosis group. Both continuous and dotted heavy lines represent the median function curves. Both shaded areas represent the interquartile range. p-values were obtained using a non-parametric Log-rank test to compare switchers’ and initiators’ curves.