TIME USAGE AND HCP SATISFACTION AND PREFERENCE FOR SUBCUTANEOUS (SC) VERSUS INTRAVENOUS (IV) NATALIZUMAB: A MULTI-COUNTRY TIME AND MOTION (T&M) STUDY

Oliver-Smith P[1], Acosta C[1], Jomaa K[2], Menon J[3], Sandor R[4], De Cock E[5]

[1]Biogen, Baar, Switzerland, [2]Former employee of Biogen, Baar, Switzerland, [3]Former employee of Syneos Health, Aarhus, Denmark, [4]Former employee of Syneos Health, Hungary, [5]Syneos Health, Barcelona, Spain.

Objective

- To quantify active healthcare professional (HCP) time, patient time, HCP satisfaction and preference for natalizumab subcutaneous (SC) compared to intravenous (IV) in treating relapsing-remitting multiple sclerosis (RRMS) patients.

Conclusions

- This study showed substantial reductions in active HCP time, drug administration time, and chair time for natalizumab SC compared to IV in 7 sites across 3 countries.
- HCPs who participated in the survey reported an increase in their level of satisfaction with SC and showed a clear preference for SC over IV.
- Utilizing natalizumab SC instead of IV could lead to substantial savings in HCP time, which could be redeployed to other patient care activities. In centers operating at capacity, chair time being freed up could be used to treat new patients and therefore improve the efficiency of healthcare delivery.

Introduction

- Multiple sclerosis (MS) is a chronic autoimmune disease leading to inflammation, demyelination, development of lesions and progressive disability (Zuvich et al., 2009).
- In 2020, estimated prevalence of MS in Europe was 143 per 100,000 population (Walton et al. 2020), of which ~85% have RRMS (Ziemssen et al., 2020).
- Natalizumab SC, with efficacy and safety similar to natalizumab intravenous (IV) (Trojano et al.,2021), is expected to reduce preparation/administration duration and may increase convenience for patients and HCPs.
- Though prior research estimated reduced patient and HCP time associated with natalizumab SC vs. IV (Filippi et al, 2024), a lack of real-world data on time efficiencies associated with its use in Europe remains.

Figure 1. Natalizumab IV and SC Preparation and Administration Tasks

IV		SC
Preparation	**Administration**	**Administration***
Collect natalizumab IV vial for preparation	Collect natalizumab infusion bag and consumables	Collect natalizumab SC and consumables
Prepare natalizumab infusion bag	Install venous catheter/ line flush/ blood draw	Natalizumab SC administration (2 injections)
Waste disposal after preparation	Infusion initiation	Waste disposal after administration
Record-keeping after preparation	Patient check-ups during infusion	Record-keeping related to natalizumab SC administration
Leave natalizumab infusion bag ready for collection	Infusion completion	Patient post-injection observation
	Waste disposal after administration	*SC preparation workflow is not applicable.
	Record-keeping related to natalizumab IV administration	
	Patient post-infusion observation	

Methods

Study Design

- Observational T&M study at 7 sites across 3 countries: France (3), Spain (3), and the United Kingdom (1).
- At each site, 1 HCP experienced in natalizumab IV and SC preparation and administration workflows completed a semi-structured interview and site-specific Case Report Forms (CRFs) were built (Figure 1).
- Staff received standardized training, collected data using stopwatches, recorded data on paper CRFs, and transferred data to electronic CRFs (Excel).
- A generalized linear mixed model was used to analyse pooled data of total active HCP time and patient time and explore impact of administration route on both endpoints.
- HCPs who were involved in observed IV and SC preparation and/or administration processes (i.e., pharmacy staff, nursing staff) were eligible to complete a one-time satisfaction and preference survey (25 surveys completed).

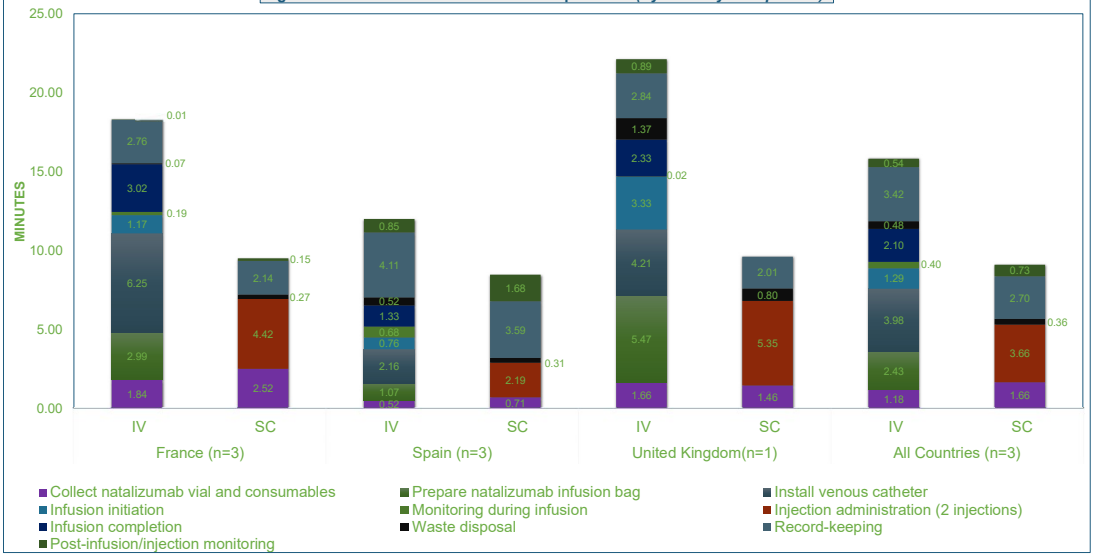
Results

- In total, **102 IV observations** were collected:
  - 38 in France (3 sites).
  - 49 in Spain (3 sites).
  - 15 in the UK (1 site).
- In total, **111 SC observations** were collected:
  - 22 in France (3 sites).
  - 44 in Spain (3 sites).
  - 15 in the UK (1 site).
- Mean total active HCP time (minutes) per visit was **reduced by 42.5%** across all sites (15.83 for IV vs. 9.11 for SC, p<0.0001); -29.3% (Spain), -48.1% (France), and -56.5% (UK); annual reduction in active HCP time per patient was 87.4 minutes (Figures 2 and 3).
- Mean patient chair time (minutes) per visit was **reduced by 64.9%** (95.18 for IV vs. 33.45 for SC, p<0.0001); -60.4% (Spain), -67.3% France), and -69.2% (UK); annual reduction in patient infusion chair time was 13 hours (21.4 for IV vs. 8.4 for SC) (Figure 4).
- Time for administration only (infusion or injection) was **reduced by 93%** (54.06 for IV vs. 3.66 for SC, <0.0001).
- **Mean HCP satisfaction score for administration was higher for SC** compared to IV (9.21 vs. 8.17; p=0.0256) (Figure 5). No statistical difference was seen for preparation (8.44 for IV vs. 9.17 for SC; p=0.1034).
- **70% stated a preference for SC** (30% "no preference"), of which 56% "very strong" and 19% "fairly strong".
  - "Ease of drug preparation" (2.86) and "Time needed for drug preparation" (3.29) are the most important reasons for HCP's preference of natalizumab SC preparation over IV.
  - "Ease of drug administration" (2.31) and "Time needed for drug administration" (3.38) are the most important reasons for HCP's preference of natalizumab SC administration over IV (Figure 6).

Limitations

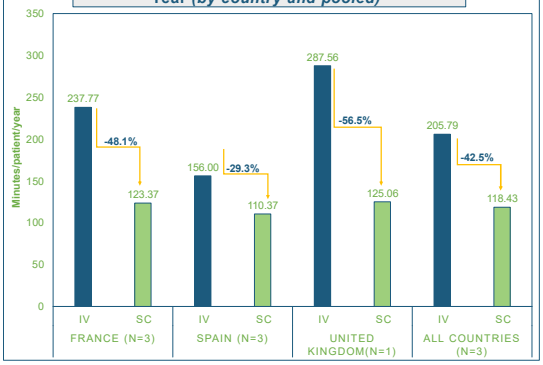
- This study was conducted in a small number of countries and centres and not meant to generate generalizable results. As with all T&M studies, results are only valid for the sites/settings where the study is conducted but can offer valuable insights into what may be expected at a broader country level.

Figure 2. Mean Total Active HCP Time per Visit *(by country and pooled)



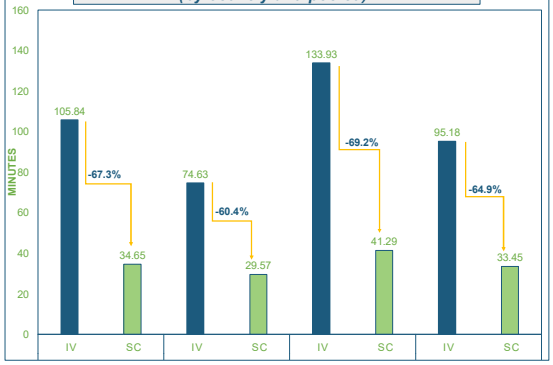
* Arithmetic mean across all observations and countries.

Figure 3. Annual Active HCP Time per Patient per Year *(by country and pooled)



*Assuming that natalizumab administration frequency is 13 times/year. Arithmetic mean (from SAS output).

Figure 4. Mean Total Patient Time in Chair per Visit *(by country and pooled)



*Time per visit multiplied by 13 annual visits (administration every 4 weeks). Arithmetic mean (from SAS output).

Figure 5. HCP Satisfaction with Natalizumab SC vs. IV (*by country and pooled*)

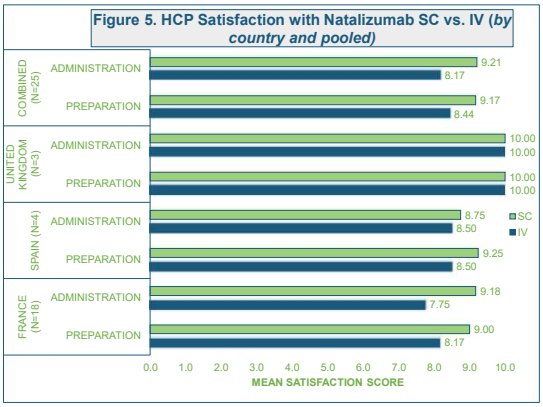
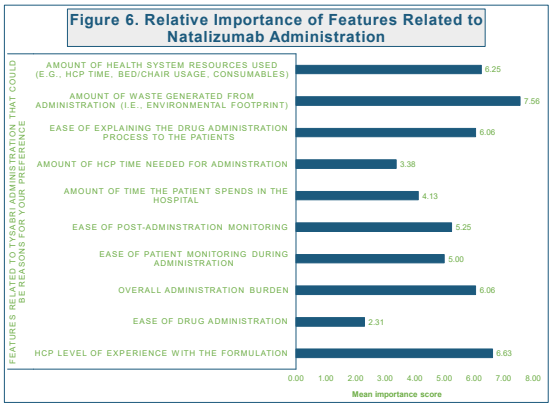


Figure 6. Relative Importance of Features Related to Natalizumab Administration



References: Filippi M, Grimaldi L, Conte A, Totaro R, Valente MR, Maiuchi S, Granella F, Cordioli C, Brescia Morra V, Zanetta C, Perini D, Santoni L; EASIER Study Working Group. Intravenous or subcutaneous natalizumab in patients with relapsing-remitting multiple sclerosis: investigation on efficiency and savings-the EASIER study. J Neurol. 2024 Jan;271(1):340-354. Trojano M, Ramió-Torrentà L, Grimaldi LM, et al. A randomized study of natalizumab dosing regimens for relapsing-remitting multiple sclerosis. Mult Scler. 2021;27:2240–2253.; Walton C, King R, Rechtman L, Kaye W, Leray E, Marrie RA, Robertson N, La Rocca N, Uitdehaag B, van der Mei I, Wallin M, Helme A, Angood Napier C, Rijke N, Baneke P. Rising prevalence of multiple sclerosis worldwide: Insights from the Atlas of MS, third edition. Mult Scler. 2020 Dec;26(14):1816-1821.; Ziemssen T, Tolley C, Bennett B, Kilgariff S, Jones E, Pike J, Tomic D, Piani-Meier D, Lahoz R. A mixed methods approach towards understanding key disease characteristics associated with the progression from RRMS to SPMS: Physicians' and patients' views. Mult Scler Relat Disord. 2020 Feb;38:101861.; Zuvich RL, McCauley JL, Pericak-Vance MA, Haines JL. Genetics and pathogenesis of multiple sclerosis. Semin Immunol. 2009;21(6):328-333.

Acknowledgements: Writing and editorial support for the preparation of this poster was provided by Syneos Health (North Carolina, USA): study funding was provided by Biogen.

Disclosure: P Oliver-Smith and C Acosta are current employees of Biogen and may hold stock in the company.