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To Whom It May Concern:

Sabine has supported our Roche Biostatistics and Data science departments as a freelancer as of July 1st, 2011 until January 31st, 2021 with on average 50% of a full time equivalent (0.5 FTE). Due to ongoing evolution of our company's data science community including the external resourcing strategy, Sabine's employment in our biostatistics and data science departments could unfortunately not be extended. Sabine and myself have been working directly together on various number of diverse therapeutics projects in oncology along the life cycles of the therapeutics including research & development, regulatory submissions (FDA, EMA, and many other health authorities globally) as well as medical activities around marketed therapeutics. Next to the variety of activities such as developing clinical development plans including designing, and execution of studies and discussing results with various stakeholders including the forth-mentioned regulators, Sabine has also been involved in different working groups around development and deployment of novel statistical methodologies. A particular highlight being her instrumental work on developing a novel and innovative approach to analyze anti-drug antibodies of cancer immunotherapies, and being a core member of the implementation team deploying this methodology to a large number of studies via implementing a semi-automated workflow including automated interpretation of results, significantly enhancing efficiency in execution and report writing.

Overall, she provided excellent statistical but also strategic drug development of different therapeutics. She was a core member and contributor, ranging from various clinical trial teams up to global teams such as the global development teams and life cycle teams. She co-created the journey of therapeutics to patients such as supporting the development of a subcutaneous formulation (including work on an administration device) for oncology products for an improved patient experience and determining the most appreciate treatment duration with therapeutics for patients to maximize outcome. Sabine was integral for many regulatory submissions word-wide, including also direct participation in health authority meetings. To name a few, Sabine contributed to the approval of Herceptin Hylecta (subcutaneous formulation of the transformative therapeutics of Herceptin for breast cancer) in the EU and US, the label updates in the EU to include guidance on treatment switches based on innovative analyses of medical affairs trials. Most recently, Sabine has been involved in the ongoing regulatory interactions around anti-drug antibodies for biologics applying the new ICH E9 (R1) addendum with its principal stratum strategy.

Sabine is a strong statistician with a great combination of methodological strength paired with strong application and programming excellence. Sabine has an agile mindset, she does not hesitate to speak up, and she has a high work ethic and has good influential skills to bring her great ideas forward to the clinical teams and other stakeholders. Sabine is very enjoyable and impressive to work with.

I highly recommend Sabine Lauer to any other company. I am convinced that she will prove herself to be a highly influential, productive and impactful member of any team requiring a highly talented statistician.

Sincerely,

Dominik Heinzmann
January 31st, 2021