

Sentiment analysis of health authority feedback

David Ruau Eren M. Elçi
david.ruau@bayer.com and eren.elci@bayer.com

August 9, 2018

Bayer, like any pharmaceutical company, has to submit scientific evidence and (clinical trial) data to support an application for a new drug or a new indication for an existing drug. The European Medicine Agency (EMA) is the central health authority in Europe and is, among other things, responsible for this application process (in addition to country specific authorities).

Following an application by a pharmaceutical company and an extensive scientific evaluation the EMA publishes an *European Public Assessment Report* (EPARs). EPARs are freely available and importantly contain the scientific evaluation of an application and reasons that led to refusal or approval.

Bayer's Regulatory Intelligence department has provided you with a dataset that contains 266 sentences, that were extracted from randomly selected EPARs. Importantly, these sentences were extracted from the corresponding EPAR section that evaluates the **setup and parameters of clinical trials**. For each sentence the regulatory colleagues further specified its *sentiment*, which can either be *neutral*, *negative* or *positive*.

Your task is to **check the feasibility of an automated sentiment analysis tool for EPARs**, ultimately helping the regulatory colleagues to quickly identify (sub-) optimal clinical trial properties and learn from competitor activities.

You might consider the following questions in order to focus your work:

- Is the dataset balanced?
- Is the amount of data sufficient for allowing a hold-out dataset?
- Do you have enough data to consider deep neural architectures or might good feature engineering with more shallow models suffice?

- During the data collection process, for some sentences multiple experts disagreed on the sentiment of a given sentence, how could you capture such an ambiguity in your model and potentially notify users about such unclear instances?
- How does your model come to a specific conclusion, what about model interpretability?
- Think beyond the pure sentiment analysis of sentences, e.g. how would you automatically extract *relevant* sentences from EPARs and ensure that the analysis is only applied to specific sections? It is worth to explore some EPARs on the EMA website (e.g. consider the ones for Bayer products Eylea¹ or Xarelto²).

¹http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-Public_assessment_report/human/002392/WC500135744.pdf

²http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-Public_assessment_report/human/000944/WC500057122.pdf